

STIC Search Report

STIC Database Tracking Number: 102526

TO: Mital Patel

Location: CP2, 3B30

Art Unit: 3761

Case Serial Number: 10/035199

From: Jeanne Horrigan

Location: EIC 3700

CP2-2C08

Phone: 305-5934

jeanne.horrigan@uspto.gov

Search Notes

Attached are the search results for the mask fit test, including author and prior art searches in foreign and international patent databases, and prior art searches in medical and general sci/tech information in non-patent literature databases and on the Internet, through the Google and Scirus search engines.

Also attached is a search feedback form. Completion of the form is voluntary. Your completing this form would help us improve our search services.

I hope the attached information is useful. Please feel free to contact me (phone 305-5934 or email jeanne.horrigan@uspto.gov) if you have any questions or need additional searching on this application.



EIC 3700

Questions about the scope or the results of the search? Contact the EIC searcher or contact:

John Sims, EIC 3700 Team Leader 308-4836, CP2-2C08

Vo	luntary Results Feedback Form
>	I am an examiner in Workgroup: Example: 3730
>	Relevant prior art found, search results used as follows:
	102 rejection
	103 rejection
	Cited as being of interest.
	Helped examiner better understand the invention.
	Helped examiner better understand the state of the art in their technology.
	Types of relevant prior art found:
	☐ Foreign Patent(s)
	 Non-Patent Literature (journal articles, conference proceedings, new product announcements etc.)
\triangleright	Relevant prior art not found:
	Results verified the lack of relevant prior art (helped determine patentability).
	Results were not useful in determining patentability or understanding the invention.
Co	mments:

Drop off or send completed forms to STIC/EIC3700 CP2 2C08



September 3, 2003 File 350: Derwent WPIX 1963-2003/UD, UM &UP=200355 File 347: JAPIO Oct 1976-2003/Apr (Updated 030804) File 371: French Patents 1961-2002/BOPI 200209 Items Description S1 1 AU='BREWER G N' S2 4 AU='COLLA G A' s3 6 AU='FARRUGIA S' OR AU='FARRUGIA S P' S4 1 AU='SOMAIYA C' AU='BREWER G' S5 8 **S6** 5 AU='COLLA G' (S1 OR S5) AND (S2 OR S6) AND S3 AND S4 s7 S8 8 MASK() FIT (S1:S6 AND S8) NOT S7 S9 0 S10 180482 MASK OR MASKS S11 5 (S1:S6 AND S10) NOT S7 7/34/1 (Item 1 from file: 350) DIALOG(R) File 350: Derwent WPIX (c) 2003 Thomson Derwent. All rts. reserv. 013303508 **Image available** WPI Acc No: 2000-475443/200041 Mask fit pressure determination method involves determining percentile pressure of previous ventilatory assistance session Patent Assignee: RESMED LTD (RESM-N); BREWER G N (BREW-I); COLLA G A (COLL-I); FARRUGIA S P (FARR-I); SOMAIYA C (SOMA-I) Inventor: BREWER G N ; COLLA G A ; FARRUGIA S P ; SOMAIYA C Number of Countries: 091 Number of Patents: 008 Patent Family: Patent No Kind Date Applicat No Kind Date Week A1 20000629 WO 99AU1130 200041 WO 200037135 Α 19991221 20000712 AU 200022683 19991221 200048 AU 200022683 Α Α 200063 20001109 AU 9965370 19991221 AU 9965370 Α Α A1 20011017 EP 99966774 19991221 200169 EP 1144036 Α WO 99AU1130 19991221 Α US 20020056452 Al 20020516 US 99469954 A 19991221 200237 US 200235199 20020104 Α 20020730 US 99469954 US 6425395 B1 Α 19991221 200254 AU 9965370 AU 750761 В 20020725 Α 19991221 200260 20021002 WO 99AU1130 19991221 JP 2002532207 W Α 200279 JP 2000589242 19991221 Α Priority Applications (No Type Date): AU 987831 A 19981221 Patent Details: Filing Notes Patent No Kind Lan Pg Main IPC WO 200037135 A1 E 21 A61M-016/06 Designated States (National): AE AL AM AT AU AZ BA BB BG BR BY CA CH CN CR CU CZ DE DK DM EE ES FI GB GD GE GH GM HR HU ID IL IN IS JP KE KG KP KR KZ LC LK LR LS LT LU LV MA MD MG MK MN MW MX NO NZ PL PT RO RU SD SE SG SI SK SL TJ TM TR TT TZ UA UG US UZ VN YU ZA ZW Designated States (Regional): AT BE CH CY DE DK EA ES FI FR GB GH GM GR IE IT KE LS LU MC MW NL OA PT SD SE SL SZ TZ UG ZW AU 200022683 A A61M-016/06 Based on patent WO 200037135 AU 9965370 А A61M-016/06 EP 1144036 Al E A61M-016/06 Based on patent WO 200037135 Designated States (Regional): AL AT BE CH CY DE DK ES FI FR GB GR IE IT LI LT LU LV MC MK NL PT RO SE SI

A62B-007/00

Div ex application US 99469954

ASRC Searcher: Jeanne Horrigan

Serial 10/035199

US 20020056452 Al

2

Serial 10/035199 September 3, 2003

US 6425395 B1 A61M-016/00

AU 750761 B A61M-016/06 Previous Publ. patent AU 9965370

JP 2002532207 W 22 A61M-016/06 Based on patent WO 200037135

Abstract (Basic): WO 200037135 Al

NOVELTY - The mask fit pressure determination method involves determining percentile pressure of previous ventilatory assistance session. The determined percentile pressure is the test pressure chosen from range of 75th-95th percentile pressure.

DETAILED DESCRIPTION - The base pressure ranging from 10-12cm H2O, is set as test pressure when previous percentile pressure is not determined. When the pressure ventilatory assistance session is occurred for greater than predetermined time interval of three hours, the previous pressure is determined. INDEPENDENT CLAIMS are also included for the following:

- (a) mask correct fitting assessing method;
- (b) ventilatory assistance apparatus

USE - For determination of suitable pressure for fitting mask used for patients having obstructive sleep apnea (OSA) or other breathing disorders.

ADVANTAGE - The mask fit pressure is determined by previous percentile pressure by hence when mask fitted to patient, the leaks are prevented. The treatment efficacy depends on correct mask fitting.

DESCRIPTION OF DRAWING(S) - The figure shows the schematic block diagram of continuous positive airway pressure apparatus describing mask fitting pressure determination method.

pp; 21 DwgNo 2/3

Derwent Class: P34; P35; S02; S05

International Patent Class (Main): A61M-016/00; A61M-016/06; A62B-007/00 International Patent Class (Additional): A62B-009/00

11/26,TI/1 (Item 1 from file: 350)

DIALOG(R) File 350: Derwent WPIX

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015493373

WPI Acc No: 2003-555520/200352

Continuous positive airway pressure treatment pressure administration method for treating sleep apnea syndrome, involves increasing pressure of air supplied to patient when detecting apnea

11/26,TI/2 (Item 2 from file: 350)

DIALOG(R) File 350: Derwent WPIX

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013204459

WPI Acc No: 2000-376332/200032

Fault detection in a continuous positive airway pressure device for the treatment of sleeping disorders such as obstructive sleep apnea using a controlled gas flow generator and delivery circuit with reduced costs and improved safety

11/26,TI/3 (Item 3 from file: 350)

DIALOG(R) File 350: Derwent WPIX

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012541139

WPI Acc No: 1999-347245/199929

Administering CPAP treatment for upper airway obstruction incidences e.g. sleep Apnea

1

ASRC Searcher: Jeanne Horrigan

Serial 10/035199 September 3, 2003

11/26,TI/4 (Item 4 from file: 350)

DIALOG(R) File 350: Derwent WPIX

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011224095

WPI Acc No: 1997-202020/199718

Continuous positive airway pressure treatment apparatus with pressure swing compensation - estimates flow from measured and closed valve pressures with square root of estimate used to linearise flow

11/26,TI/5 (Item 5 from file: 350)

DIALOG(R) File 350: Derwent WPIX

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011130839

WPI Acc No: 1997-108763/199710

Auto-calibration of pressure transducer offset - determines if flow generator is operating and if transducer senses no pressure to accept transducer's pressure offset value as being atmospheric ASRC Searcher: Jeanne Horrigan Serial 10/035199 September 3, 2003 File 348: EUROPEAN PATENTS 1978-2003/Aug W04 File 349:PCT FULLTEXT 1979-2002/UB=20030828,UT=20030821 Items Description S1 2 AU='BREWER GREGORY NEWTON' AU='COLLA GREG' OR AU='COLLA GREGORY ALAN' s2 s3 AU='FARRUGIA STEVEN PAUL' S 4 2 AU='SOMAIYA CHINMAYEE' S5 2 S1 AND S2 AND S3 AND S4 s6 8 S1:S4 NOT S5 a duplicate of 7/34/1 page 1 5/3,AB/2 (Item 1 from file: 349) DIALOG(R) File 349: PCT FULLTEXT (c) 2003 WIPO/Univentio. All rts. reserv. 00573762 DETERMINATION OF MASK FITTING PRESSURE AND CORRECT MASK FIT DETERMINATION DE LA PRESSION D'AJUSTEMENT D'UN MASQUE, ET AJUSTEMENT CORRECT DUDIT MASQUE Patent Applicant/Assignee: RESMED LIMITED, BREWER Gregory Newton, COLLA Gregory Alan, FARRUGIA Steven Paul, SOMAIYA Chinmayee, Inventor(s): BREWER Gregory Newton , COLLA Gregory Alan , FARRUGIA Steven Paul , SOMAIYA Chinmayee Patent and Priority Information (Country, Number, Date): Patent: WO 200037135 A1 20000629 (WO 0037135) Application: WO 99AU1130 19991221 (PCT/WO AU9901130) Priority Application: AU 987831 19981221 Designated States: AE AL AM AT AU AZ BA BB BG BR BY CA CH CN CR CU CZ DE DK DM EE ES FI GB GD GE GH GM HR HU ID IL IN IS JP KE KG KP KR KZ LC LK LR LS LT LU LV MA MD MG MK MN MW MX NO NZ PL PT RO RU SD SE SG SI SK SL TJ TM TR TT TZ UA UG US UZ VN YU ZA ZW GH GM KE LS MW SD SL SZ TZ UG ZW AM AZ BY KG KZ MD RU TJ TM AT BE CH CY DE DK ES FI FR GB GR IE IT LU MC NL PT SE BF BJ CF CG CI CM GA GN GW ML MR NE SN TD TG Publication Language: English Fulltext Word Count: 4641 English Abstract CPAP treatment apparatus (10), as one form of positive pressure

CPAP treatment apparatus (10), as one form of positive pressure ventilatory assistance, is disclosed. A turbine/blower (14), operated by a mechanically coupled electrical motor (16), receives air or breathable gas at an inlet (18) thereof, and supplies the breathable gas at a delivery pressure to a delivery tube/hose (20) having connection at the other end thereof with a nose mask (12). A microcontroller (38) has an operational "Mask-Fit" mode. An initial constant pressure level is applied by the blower (14) to the mask (12). If the functional mode is a Manual mode, then the mask-fit test pressure is the current 'set' pressure. If the functional mode is the Automatic Titration mode, the mask-fit test pressure is the 95th percentile pressure of the previous session, otherwise it is the base treatment pressure, e.g. 10-12 cm H2O. This constant pressure is applied for a period of time, typically 1-3 minutes. The microcontroller (38) continuously determines mask leak as the value, fLEAK, from a flow sensor (32), comparing this to a threshold,

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ASRC Searcher: Jeanne Horrigan

Serial 10/035199 September 3, 2003

and providing the patient with a visual indication of degree of leak. In this way the patient can manipulate the mask to ensure correct fitting as indicated by the appropriate message or indication.

6/6/2 (Item 2 from file: 348)

01057212

ADMINISTRATION OF CPAP TREATMENT PRESSURE IN PRESENCE OF APNEA

6/6/3 (Item 3 from file: 348)

00848391

FLOW ESTIMATION AND COMPENSATION OF FLOW-INDUCED PRESSURE SWINGS IN CPAP TREATMENT AND ASSISTED RESPIRATION

6/6/5 (Item 2 from file: 349)

00492747 **Image available**

ADMINISTRATION OF CPAP TREATMENT PRESSURE IN PRESENCE OF APNEA

6/6/6 (Item 3 from file: 349)

00369691 **Image available**

FLOW ESTIMATION AND COMPENSATION OF FLOW-INDUCED PRESSURE SWINGS IN CPAP TREATMENT AND ASSISTED RESPIRATION

6/6/7 (Item 4 from file: 349)

00361739 **Image available**

AUTO-CALIBRATION OF PRESSURE TRANSDUCER OFFSET

6/6/8 (Item 5 from file: 349)

00349542 **Image available**

MONITORING THE OCCURRENCE OF APNEIC AND HYPOPNEIC AROUSALS

6/3,AB/4 (Item 1 from file: 349)

DIALOG(R) File 349: PCT FULLTEXT

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00564084

FAULT DIAGNOSIS IN CPAP AND NIPPV DEVICES

DIAGNOSTIC D'ANOMALIES DANS LES DISPOSITIFS DE VENTILATION SPONTANEE EN PRESSION POSITIVE CONTINUE (CPAP) ET DE VENTILATION NON INVASIVE EN PRESSION POSITIVE (NIPPV)

Patent Applicant/Assignee:

RESMED LTD,

COLLA Greq,

KENYON Barton,

Inventor(s):

COLLA Greg ,

KENYON Barton

Patent and Priority Information (Country, Number, Date):

Patent: WO 200027457 A1 20000518 (WO 0027457)
Application: WO 99AU972 19991105 (PCT/WO AU9900972)

Priority Application: AU 986933 19981105

Designated States: AE AL AM AT AU AZ BA BB BG BR BY CA CH CN CR CU CZ DE DK

DM EE ES FI GB GD GE GH GM HR HU ID IL IN IS JP KE KG KP KR KZ LC LK LR

LS LT LU LV MA MD MG MK MN MW MX NO NZ PL PT RO RU SD SE SG SI SK SL TJ

TM TR TT TZ UA UG US UZ VN YU ZA ZW GH GM KE LS MW SD SL SZ TZ UG ZW AM

AZ BY KG KZ MD RU TJ TM AT BE CH CY DE DK ES FI FR GB GR IE IT LU MC NL

PT SE BF BJ CF CG CI CM GA GN GW ML MR NE SN TD TG

Publication Language: English

Serial 10/035199 September 3, 2003

Fulltext Word Count: 5343

English Abstract

A ventilation device for non-invasive positive pressure ventilation (NIPPV) or continuous positive airway pressure (CPAP) treatment of a patient has a gas flow generator (1, 2), a gas delivery circuit (5, 6) optionally including a humidifier (H), a controller (4) and sensors (10, 11, 12, 13, 14) monitoring values of operational parameters of the device. The device further includes one or more relationships stored in data storage of the controller relating combinations of parameter values as being indicative of fault conditions of the device operation, the sensors and/or the fault detection process.

ASRC Searcher: Jeanne Horrigan Serial 10/035199 September 3, 2003 File 155:MEDLINE(R) 1966-2003/Aug W5 File 5:Biosis Previews(R) 1969-2003/Aug W4 File 73:EMBASE 1974-2003/Aug W4 File 34:SciSearch(R) Cited Ref Sci 1990-2003/Aug W4 File 434:SciSearch(R) Cited Ref Sci 1974-1989/Dec Set Items Description S1 357 AU='BREWER G' OR AU='BREWER G N' OR AU='BREWER G.' AU='BREWER GREG' OR AU='BREWER GREGORY NEWTON' S2 AU='COLLA G' OR AU='COLLA G.' OR AU='COLLA G-A' OR AU='COLs3 88 LA GREGORY ALAN' AU='FARRUGIA S' OR AU='FARRUGIA S.' OR AU='FARRUGIA STEVEN S 4 11 PAUL' AU='SOMAIYA CHINMAYEE' S5 1 S6 50807 MASK OR MASKS s7 1783020 PRESSURE S8 3 S1:S5 AND S6(S)S7 S9 2 RD (unique items) (Item 1 from file: 5) BIOSIS NO.: 200300121903 14127874 Administration of CPAP treatment pressure in presence of apnea. 2003 (Item 2 from file: 5) 9/7/2 DIALOG(R)File 5:Biosis Previews(R) (c) 2003 BIOSIS. All rts. reserv. 13848431 BIOSIS NO.: 200200477252 Determination of mask fitting pressure and correct mask fit. AUTHOR: Brewer Gregory Newton (a); Colla Gregory Alan; Farrugia Steven Paul ; Somaiya Chinmayee AUTHOR ADDRESS: (a) Lewisham**Australia JOURNAL: Official Gazette of the United States Patent and Trademark Office Patents 1260 (5):pNo Pagination July 30, 2002 MEDIUM: e-file ISSN: 0098-1133 DOCUMENT TYPE: Patent RECORD TYPE: Abstract LANGUAGE: English ABSTRACT: A CPAP treatment apparatus, as one form of positive pressure ventilatory assistance, includes a turbine/blower, operated by a mechanically coupled electrical motor that receives air or breathable gas

ANGUAGE: English
BSTRACT: A CPAP treatment apparatus, as one form of positive pressure
ventilatory assistance, includes a turbine/blower, operated by a
mechanically coupled electrical motor that receives air or breathable gas
at an inlet thereof, and supplies the breathable gas at a delivery
pressure to a delivery tube/hose having a connection at the other end
thereof with a nose mask. A microcontroller has an operational "Mask
-Fit" mode. An initial constant pressure level is applied by the blower
to the mask. If the functional mode is a manual mode, then the mask
-fit test pressure is the current 'set' pressure. If the functional
mode is the automatic titration mode, the mask -fit test pressure is
the 95th percentile pressure of the previous session, otherwise it is
the base treatment pressure, e.g. 10-12 cm H2 O. This constant
pressure is applied for a period of time, typically 1-3 minutes. The
microcontroller continuously determines mask leak as the value, fLEAK,
from a flow sensor, comparing this to a threshold, and providing the
patent with a visual indication of degree of leak. In this way the
patient can manipulate the mask to ensure correct fitting as indicated
by the appropriate message or indication.

ASRC Searcher: Jeanne Horrigan Serial 10/035199 September 3, 2003 File 155:MEDLINE(R) 1966-2003/Aug W5 File 5:Biosis Previews (R) 1969-2003/Aug W4 File 73:EMBASE 1974-2003/Aug W4 File 34:SciSearch(R) Cited Ref Sci 1990-2003/Aug W4 File 434:SciSearch(R) Cited Ref Sci 1974-1989/Dec File 144: Pascal 1973-2003/Aug W4 File 2:INSPEC 1969-2003/Aug W4 File 6:NTIS 1964-2003/Aug W5 File 8:Ei Compendex(R) 1970-2003/Aug W4 File 94:JICST-EPlus 1985-2003/Aug W5 File 95:TEME-Technology & Management 1989-2003/Aug W3 File 99: Wilson Appl. Sci & Tech Abs 1983-2003/Jul File 35:Dissertation Abs Online 1861-2003/Aug File 65:Inside Conferences 1993-2003/Aug W5 Set Items Description 134294 MASK? ? S1 67623 RESPIRATOR OR RESPIRATORS OR VENTILATOR OR VENTILATORS OR -52 CPAP OR CONTINUOUS() POSITIVE() AIRWAY() PRESSURE s3 728892 FIT OR FITS OR FITTED OR FITTING S4 8432083 TEST OR TESTS OR TESTED OR TESTING 3273227 PRESSURE S5 315641 LEAK???? S6 S7 602 S1(S)S3(S)S4 S8 206 S2 AND S7 S9 34855 S5 AND S6 S10 43 S8 AND S9 S11 21 RD (unique items) S12 2 S11/2003 1 S11/2002 [a duplicate] S13 S14 18 S11 NOT S12:S13 18 Sort S14/ALL/PY,D S15 15/6/11 (Item 11 from file: 155) 07534056 92397850 PMID: 1524028 Characteristics of face seal leakage in filtering facepieces. Sep 1992 (Item 14 from file: 35) 15/6/14 01232902 ORDER NO: AAD92-05414 AEROSOL FILTRATION AND FACESEAL LEAKAGE CHARACTERISTICS OF FILTERING **FACEPIECES** Year: 1991 15/6/17 (Item 17 from file: 35) 932576 ORDER NO: AAD86-22286 PARTICLE SIZE - DEPENDENT LEAKAGE THROUGH THE FACESEAL OF NEGATIVE-PRESSURE HALF-MASK RESPIRATORS (AEROSOIS, SAFETY) Year: 1986

15/6/18 (Item 18 from file: 155)
04507743 84150500 PMID: 6702601
Effect of facial hair on the face seal of negative-pressure respirators.
Jan 1984

15/7/1 (Item 1 from file: 155)
DIALOG(R)File 155:MEDLINE(R)

1

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08816526 20099771 PMID: 10633954

Effect of test exercises and mask donning on measured respirator fit.

Crutchfield C D; Fairbank E O; Greenstein S L

Environmental and Occupational Health, Arizona Prevention Center, University of Arizona, Tucson, USA.

Applied occupational and environmental hygiene (ENGLAND) Dec 1999, 14 (12) p827-37, ISSN 1047-322X Journal Code: 9103256

Document type: Journal Article

Languages: ENGLISH

Main Citation Owner: NLM Record type: Completed

Quantitative respirator fit test protocols are typically defined by a series of fit test exercises. A rationale for the protocols that have been developed is generally not available. There also is little information available that describes the effect or effectiveness of the fit test exercises currently specified in respiratory protection standards. This study was designed to assess the relative impact of fit test exercises fit as measured by a controlled and mask donning on respirator negative pressure and an ambient aerosol fit test system. Multiple donnings of two different sizes of identical respirator models by each of test subjects showed that donning affects respirator fit to a greater degree than fit test exercises. Currently specified fit test exercises, and the determination of fit is protocols emphasize test based on a single mask donning. A rationale for a modified fit test protocol based on fewer, more targeted test exercises and multiple mask donnings is presented. The modified protocol identified inadequately respirators as effectively as the currently specified fitting Occupational Safety and Health Administration (OSHA) quantitative fit test protocol. The controlled negative pressure system measured significantly (p < 0.0001) more respirator leakage than the ambient aerosol fit test system. The bend over fit test exercise was found to be predictive of poor respirator fit by both fit test systems. For the better fitting respirators, only the talking exercise generated factors that were significantly lower (p < 0.0001) than fit corresponding donning fit factors.

Record Date Created: 20000208
Record Date Completed: 20000208

15/7/2 (Item 2 from file: 155)

DIALOG(R) File 155: MEDLINE(R)

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10974286 97327048 PMID: 9183835

Effect of leak location on measured respirator fit.

Crutchfield C D; Park D L

University of Arizona, Division of Community, Tucson 85719, USA.

American Industrial Hygiene Association journal (UNITED STATES) Jur 1997, 58 (6) p413-7, ISSN 0002-8894 Journal Code: 0371160

Document type: Journal Article

Languages: ENGLISH

Main Citation Owner: NLM Record type: Completed

A significant difference in **leak** detection as a function of **leak** location was observed during a study assessing how well current models of quantitative **fit-test** systems detect **leakage**. Known sources of **leakage** (matched hypodermic needles) were introduced at three fixed locations into factory-

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probed half-mask and full-face respirators mounted on a headform-breathing machine system. The leak locations were the bridge of the nose, the cheek, and the chin. Baseline leakage into each respirator was determined by conducting a fit-test with all fixed leak sources capped. Fit tests were repeated with each individual source uncapped. Study objectives included determining (1) how well each system measured the leakage, and (2) whether leak location had any effect on leak measurement. An ambient aerosol fittest system (Portacount Plus) and a controlled negative pressure (CNP) fittest system (FitTester 3000) were used. The ambient aerosol system detected an overall average of 37.2% of the known leakage, with a coefficient of variation of 44.7%. An analysis of variance showed significant differences in aerosol system measurements of leakage as a function of leak location and mask type (p < 0.001). A different pattern of aerosol leak detection as a function of leak location was observed between half-mask and full-face respirators, which appears to be related to differences in in-mask airflow dynamics. The CNP system detected an overall average of 97.9% of the known leakage through the same hypodermic needles, with a coefficient of variation of 4.3%. CNP system results were not affected by **leak** location (p > 0.43) or mask type (p > 0.32).

Record Date Created: 19970708
Record Date Completed: 19970708

15/7/3 (Item 3 from file: 94)

DIALOG(R) File 94: JICST-EPlus

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03002683 JICST ACCESSION NUMBER: 96A1005443 FILE SEGMENT: JICST-E

A Study of Facepiece-to-face Fitting of a Gas Mask.

TANAKA SHIGERU (1); NAKAZA MASAHIRO (1); SEKI YUKIO (1); TANAKA MASAMI (2); KIMURA KAZUSHI (2); NOZAKI KOSUKE (2)

(1) Kitasato Univ. School of Allied Health Sci.; (2) Koken Ltd.

Rodo Kagaku(Journal of Science of Labour), 1996, VOL.72, NO.11, PAGE.450-454, FIG.4, TBL.1, REF.17

JOURNAL NUMBER: G0016AAP ISSN NO: 0022-443X CODEN: ROKAA

UNIVERSAL DECIMAL CLASSIFICATION: 658.382

LANGUAGE: Japanese COUNTRY OF PUBLICATION: Japan

DOCUMENT TYPE: Journal

ARTICLE TYPE: Original paper MEDIA TYPE: Printed Publication

ABSTRACT: A quantitative respirator-fitting test in the use of half and full facepieces of gas masks was carried out for ten male subjects by means of dichlorotetrafluoroethane (Freon-114) gas. The leakage rates were measured at rest and during a physical exercise in the form of a step test after asking the subjects to put on a gas mask using their own judgment. Further, leakage rates during a similar exercise were measured after performing a qualitative fit test by the negative pressure method. When the subjects put on a half mask by their own judgment, high leakage rates were obtained among individuals with little experience in wearing a gas mask. Also, in most subjects, leakage rates during an exercise were higher than those at rest. Low leakage rates were attained after performing a fit test. On the other hand, with a full facepiese, leakage rates were low and did not differ much between resting and exercise conditions. These findings suggest that when workers wear a gas mask, a fit test by the negative pressure method would be effective in assuring its satisfactory facepiece-to-face fitting. (author abst.)

ASRC Searcher: Jeanne Horrigan Serial 10/035199

September 3, 2003

DIALOG(R)File 155:MEDLINE(R)

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08628208 95316735 PMID: 7796310

[A study for the practical use of the mask fitting tester]

Narukiyo Y; Tsukashima H; Nagoya T

Department of Employee Welfare, Toto Ltd., Japan.

Sangyo eiseigaku zasshi = Journal of occupational health (JAPAN) May 1995, 37 (3) p177-85, ISSN 1341-0725 Journal Code: 9507473

Document type: Journal Article ; English Abstract

Languages: JAPANESE

Main Citation Owner: NLM Record type: Completed

The standards require replaceable dust respirators to be designed so that the wearer can easily check facepiece-to-face fitting at any time. The common practice adopted is an air leakage examination between the facepiece and the face in a negative pressure created by sealling-off inhalation area and breathing-in (called "a negative pressure method"). This method offers only subjective testing made by the wearer himself or herself, no objective testing is possible by the third party including supervisors and hygiene staff. Accordingly, we conducted the practical use test of the Mask Fitting Tester (Model MT-02, Roken type) by letting wearers to use the tester at a sanitaryware plant where workers are well instructed for how to wear respirators and also respirators are used in good care and maintenance. In addition, a questionnaire survey was conducted to investigate how wearers perceive the practical use of the Tester. The following are the conclusions of the study and the survey for the practical use of the Mask Tester. 1) At the first fitness test , when examinees wear the respirator as in the usual manner without given particular instructions, 50% of examinees are found unachieved with the leakage rate of the desired value of 5% of less. 2) All the examinees unachieved were instructed by hygiene staff followed by fitting test to leakage rate until they pass the desired value. After check their repeating this three times, there were no examinees found unachieved. 3) 88.2% of these examinees could achieve the desired value only by adjusting headbands and correcting the position of facepiece under instructions.

(ABSTRACT TRUNCATED AT 250 WORDS)
Record Date Created: 19950728
Record Date Completed: 19950728

15/7/5 (Item 5 from file: 6)

DIALOG(R) File 6:NTIS

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1979879 NTIS Accession Number: PB97-105050

Performance of Surgical Masks. Final Performance Report

(Rept. for 1 Sep 92-31 Aug 94)

Willeke, K.

Cincinnati Univ., OH. Dept. of Environmental Health.

Corp. Source Codes: 006394024

Sponsor: National Inst. for Occupational Safety and Health, Cincinnati, OH. 29 Jun 95 16p

Languages: English

Journal Announcement: GRAI9701

Sponsored by National Inst. for Occupational Safety and Health, Cincinnati, OH.

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Serial 10/035199 September 3, 2003

email at orders@ntis.fedworld.gov. NTIS is located at 5285 Port Royal Road, Springfield, VA, 22161, USA.

NTIS Prices: PC A03/MF A01

Country of Publication: United States

Contract No.: NIOSH-5-RO1-OH02948

and respirators currently in use or being considered Surgical masks for use in the health care industry were evaluated. Collection efficiencies with bacteria were compared to those with inert, nonliving test particles currently used to evaluate the performance of industrial masks and respirators . If there was an adequate face seal fit of the mask to the face of the wearer, the findings indicated that higher efficiency filters in health care masks worked better. When there was a large face seal leak , the higher performance mask may actually perform worse than a less efficient mask, as the higher pressure drop across the higher performance mask directs more air flow through the face seal leak. Spherical Streptococcus-salivarius bacteria were able to penetrate as efficiently as inert corn-oil test particles in the size range from 0.9 to 1.7 micrometers. Less penetration was noted with rod shaped bacteria. The ratio of the length to the diameter of the bacteria was an important factor. A filter 95% efficient against spherical test particles may be 97 to 97.5% effective against Mycobacterium-tuberculosis bacteria.

15/7/8 (Item 8 from file: 73)

DIALOG(R) File 73: EMBASE

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05770672 EMBASE No: 1994165302

A validation study of respirator fit testing by controlled negative pressure

Crutchfield C.D.; Ruiz A.M.; Van Ert M.D.

Division of Community/Envtl. Health, University of Arizona, 1435 N.

Fremont Avenue, Tucson, AZ 85719 United States

Applied Occupational and Environmental Hygiene (APPL. OCCUP. ENVIRON.

HYG.) (United States) 1994, 9/5 (362-366)

CODEN: AOEHE ISSN: 1047-322X DOCUMENT TYPE: Journal; Article

LANGUAGE: ENGLISH SUMMARY LANGUAGE: ENGLISH

Respirator fit testing is a fundamental part of a respiratory protection program. The development of a quantitative respirator fit test method based on controlled negative pressure (CNP) provides an alternative to standard aerosol **fit test** methods that is faster and less dependent on ambient **test** conditions. This study was conducted to evaluate the performance of a controlled negative pressure system using the method validation protocol proposed in the American National Standards Institute (ANSI) Respirator Fit Test Methods Standard. The study procedure involved measuring 100 pairs of sequential fit tests using a generated aerosol system and a controlled negative pressure system. A study population of 25 subjects was tested with both half- mask and full-face air purifying respirators . Additional fit test series were accomplished with each mask type by inserting leak sources between each subject's cheek and respirator faceseal. The leaks were used to achieve a distribution of fit test results above and below the test acceptance criterion of a fit factor of 100. Study results show that the controlled negative pressure system exceeded the ANSI validation criteria in the areas of test sensitivity, test specificity, and predictive value of a pass. The CNP system did not pass any respirators that were subsequently rejected by the aerosol system. The CNP system did not meet

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the ANSI criterion for predictive value of a fail. Thirty respirators with induced leakage exceeding 530 ml/min were rejected by the CNP system but subsequently passed the generated aerosol fit test.

15/7/9 (Item 9 from file: 95)

DIALOG(R) File 95: TEME-Technology & Management

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00808845 F94070261969

Development of a dichotomous-flow quantitative fit tester for half-mask and full-facepiece respirators

(Entwicklung eines Testverfahrens mit zweigeteiltem Fluss zur quantitativen Ueberpruefung der Passform von Halb- und Vollmaskenatemgeraeten) Krishnan, U; Willeke, K; Juozaitis, A; Lehtimaeki, M; Szewczyk, K Univ. of Cincinnati, USA

American Industrial Hygiene Association Journal, v55, n3, pp223-229, 1994 Document type: journal article Language: English

Record type: Abstract

ISSN: 0002-8894

ABSTRACT:

A new method to quantitate the fit of elastomeric half- mask and full-facepiece air-purifying respirators was developed. In this method the two flows, catridge flow and leak flow, are separate. The air-purifying cartridges of the respirator are attached to a reference respirator . A selected flow equivalent to the inhalation flow of the wearer is drawn through the cartridge pair. A feedback system consisting of a pressure controller and a control valve is used to set the pressure drop in the mask on the subject's face equal to the pressure drop in the reference mask . The faceseal leak flow is measured while the subject holds his or her breath for a short period of time. The ratio of total flow (cartidge flow + leak flow) to leak flow is a measure of fit and is defined as the flow fit factor. Aerosol fit factors and flow fit factors were determined using sampling probes in three mask locations: top, center, and bottom. A Kruskal-Wallis test showed that aerosol fit factors obtained from the three locations were significantly different from each other (p = 0.0001) while the corresponding flow **fit** fators were not. Aerosol fit factors obtained with the center probe had the least variability. The coefficient of variation in aerosol fit factors ranged from 5.4 % for the center probe to 19 % for the bottom probe; the coefficient of variation in flow fit factors was much lower, ranging from 1.7 % for the top probe to 2.2 % for the center and bottom probes.

15/7/10 (Item 10 from file: 73)

DIALOG(R) File 73: EMBASE

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05330105 EMBASE No: 1993098190

Determination of inspiratory pressures and flow rates for work rate-dependent quantitative respirator fit testing

Crutchfield C.D.; Pham T.K.; Van Ert M.D.

School of Health Related Professions, University of Arizona, Tucson, AZ 85719 United States

Applied Occupational and Environmental Hygiene (APPL. OCCUP. ENVIRON. HYG.) (United States) 1993, 8/2 (103-107)

CODEN: AOEHE ISSN: 1047-322X

DOCUMENT TYPE: Journal; Article

LANGUAGE: ENGLISH SUMMARY LANGUAGE: ENGLISH

Quantitative respirator fit testing is used to select respirators

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for individual workers and to gain insight into potential contaminant leakage . Current fit test exercises are designed to primarily challenge the respirator facepiece-to-face seal. Inspiratory pressure across any break in the seal is also an important determinant of the amount of leakage through the break. Fit tests conducted at resting respiratory patterns may not be representative of leakage that occurs at respiratory patterns employed in the workplace. By design, the controlled negative pressure fit test method can control the driving force for leakage into a respirator by selecting a challenge pressure that represents actual use inspiratory pressures. In this study, mean inspiratory pressures and flow rates were determined for males and females working at external work rates of 0, 180, 360, and 540 kg m/min. Effects of mask type and breathing resistance were determined using both half- mask and full-face respirators equipped with cartridges of relative low, medium, and high breathing resistance. Inspiratory pressure was found to be strongly dependent on work rate and cartridge resistance. Mask type and gender also had significant effects on mean inspiratory pressure . Inspiratory flow rate was significantly affected by work rate and mask type. Data from the study can be used to conduct work rate-dependent fit testing with the controlled negative pressure method.

15/7/12 (Item 12 from file: 35)

DIALOG(R)File 35:Dissertation Abs Online

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01261408 ORDER NO: AAD93-02422

DEVELOPMENT AND VALIDATION OF A DICHOTOMOUS FLOW QUANTITATIVE RESPIRATOR FIT TEST

Author: KRISHNAN, USHA

Degree: PH.D. Year: 1992

Corporate Source/Institution: UNIVERSITY OF CINCINNATI (0045)

Adviser: KLAUS WILLEKE

Source: VOLUME 53/09-B OF DISSERTATION ABSTRACTS INTERNATIONAL.

PAGE 4599. 81 PAGES

A new method to quantitate the **fit** of half- mask and full-facepiece air-purifying respirator, has been developed. It is called 'the dichotomous-flow respirator fit test'. In this method of fit testing, the user's cartridges are fitted on a reference mask and air is drawn through these cartridges at a selected flow rate. A feedback system, consisting of a pressure controller and a control valve, sets the pressure drop in the mask equal to the pressure drop in the reference mask. The in- mask leak flow rate is measured while the subject temporarily holds his or her breath and the ratio of the total flow rate (cartridge and leak flow rates combined) to the leak flow rate is determined. This ratio, defined as the 'flow fit factor', is a measure of the fit of the mask to the wearer's face. The flow fit factor was found to be independent of sampling probe location so that the probe can be located on a modified cartridge and the fit test performed with the user's own mask and cartridges.

The relationship between **pressure** drop and cartridge flow was investigated for cartridges of various types and brands. The influence of mask pressure drop on faceseal leakage was also investigated. Aerosol fit factors and flow fit factors were determined sequentially on humans. The coefficient of variation in aerosol fit factors was approximately twice those in the corresponding flow fit factors. Variation in fit factor data was used to estimate the variation in faceseal leakage during

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fit testing.

The dichotomous-flow respirator fit test is non-invasive and therefore can be used in the workplace to determine the fit of the worker's actual mask. Unlike the aerosol method that necessitates the use of HEPA cartridges during the test, the dichotomous flow method can be performed with any kind of cartridge. The system is portable and therefore convenient for field-use. It can also be used to determine the mechanical integrity of the facepiece and the exhalation valve.

15/7/13 (Item 13 from file: 155)

DIALOG(R) File 155:MEDLINE(R)

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07057410 91298294 PMID: 2069125

A feasibility study of quantitative respirator fit testing by controlled negative pressure.

Crutchfield C D; Eroh M P; Van Ert M D

School of Health Related Professions, University of Arizona, Tucson 85719.

American Industrial Hygiene Association journal (UNITED STATES) Apr 1991, 52 (4) p172-6, ISSN 0002-8894 Journal Code: 0371160

Document type: Journal Article

Languages: ENGLISH

Main Citation Owner: NLM Record type: Completed

The feasibility of using a direct measure of respirator leakage flow rate as a quantitative index of respirator face seal fit has been explored through the use of a new controlled negative pressure method. The method is based on exhausting air from a temporarily sealed respirator facepiece at a rate sufficient to generate and then sustain a constant negative pressure inside the facepiece while the wearer holds his breath. The magnitude of the negative pressure is preselected to replicate the mean inspiratory pressure inside the mask during normal wear. With the air-purifying paths into the respirator temporarily blocked, measurement of the exhaust flow rate yields a synonymous measure of the leakage flow rate into the mask during inspiration under normal use conditions. The feasibility of using the new method to quantify respirator fit was assessed in a preliminary study that compared its performance with a quantitative fit test method based on the use of dichlorodifluoromethane as a challenge agent. Study data exhibit a high degree of correlation (r greater than 0.99) and no significant difference between the two methods over a range of controlled mask leakage rates. A major advantage of the new method is that a worker can be fit tested with his assigned respirator because the method does not require a destructive sampling probe. Other significant benefits compared to current methods used to quantify respirator fit appear to include (1) ease of test administration, (2) simplicity of test components, (3) lack of a potentially toxic challenge agent, (4) a straightforward calibration procedure, (5) multiple test capability, (6) immediacy of test results, and (7) field portability of the test system.

Record Date Created: 19910813
Record Date Completed: 19910813

15/7/15 (Item 15 from file: 155)

DIALOG(R) File 155: MEDLINE(R)

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05720641 88073924 PMID: 3687730

The effect of aerosol size distribution and measurement method on

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respirator fit.

Holton P M; Willeke K

Department of Environmental Health, University of Cincinnati, OH 45267-0056.

American Industrial Hygiene Association journal (UNITED STATES) Oct 1987, 48 (10) p855-60, ISSN 0002-8894 Journal Code: 0371160

Contract/Grant No.: R01-0H-01301; PHS

Document type: Journal Article

Languages: ENGLISH

Main Citation Owner: NLM Record type: Completed

The particle size-dependent leakage into a respirator was examined by measuring the leakage of particle sizes between 0.07 to 4.4 microns through three hole sizes in a negative-pressure half-mask respirator worn by a human subject. This investigation showed that the size distribution of an aerosol test agent and the measurement method have an effect on the leakage measured in a quantitative fit test. For instance, the ratio of percent leakage measured by light scattering between test aerosols with count median diameters of 2.2 and 0.28 microns can be as large at 5:1. Likewise, the ratio of the percent leakage measured by a particle count method vs. a mass method of detection of the same polydisperse aerosol with a count median diameter equal to 2.2 microns can be as high as 4:1. The mass leakage into a mask with a leak is also greater for an exposure aerosol with a count median diameter between 0.15 to 0.30 micron compared to exposure aerosols with larger count median diameters for aerosols with the same mass concentration.

Record Date Created: 19880113
Record Date Completed: 19880113

15/7/16 (Item 16 from file: 6)

DIALOG(R) File 6:NTIS

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1299585 NTIS Accession Number: DE87005579

Powered Air-Purifying Respirator Study: Final Report

da Roza, R. A.; Cadena-Fix, C. A.; Kramer, J. E.

Lawrence Livermore National Lab., CA. Corp. Source Codes: 068147000; 9513035

Sponsor: Department of Energy, Washington, DC.

Report No.: UCRL-53757

Jul 86 33p

Languages: English

Journal Announcement: GRAI8714; NSA1200

Portions of this document are illegible in microfiche products. Original copy available until stock is exhausted. Order this product from NTIS by: phone at 1-800-553-NTIS (U.S. customers); (703)605-6000 (other countries); fax at (703)321-8547; and email at orders@ntis.fedworld.gov. NTIS is located at 5285 Port Royal Road, Springfield, VA, 22161, USA.

NTIS Prices: PC A03/MF A01

Country of Publication: United States

Contract No.: W-7405-ENG-48

Three brands of powered air-purifying respirators were subjected to a simulated-work-place study. They were worn by six human subjects while working at 80% of their cardiac reserve on a treadmill. The air flow into the respirator was controlled to match that of a respirator with a newly charged battery and with various stages of battery discharge and filter plugging. The simulation took place in a large quantitative fit

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test chamber containing PEG 400 aerosol. The penetration of aerosol into the breathing zone of the respirator, the pressure in it, and the air flow were monitored while the subject was warming up as well as during the 80% tests. The exercises recommended in ANSI Z88.2 for helmets were also used after the 80% tests were completed. The subjects were tested clean shaven, with three days' growth of stubble, and with a two-month beard growth. A striking result was that the aerosol penetration into the two-helmet respirators increased dramatically as the subjects work rate increased. On the other hand, penetration into the half mask did not change with work rate. The penetration increased as the air flow was decreased in all cases for the helmets and for beard and stubble cases for the half mask. However, for he tight- fitting half mask on a clean-shaven face, the average penetration stayed below 0.001 for all flows. 18 figs, 5 tabs. (ERA citation 12:016915)

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September 3, 2003
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File 98:General Sci Abs/Full-Text 1984-2003/Jul
     9:Business & Industry(R) Jul/1994-2003/Sep 01
File 16:Gale Group PROMT(R) 1990-2003/Sep 02
File 160:Gale Group PROMT(R) 1972-1989
File 148: Gale Group Trade & Industry DB 1976-2003/Sep 02
File 621: Gale Group New Prod. Annou. (R) 1985-2003/Sep 02
Set
        Items
                Description
S1
        70966
               MASK? ?
                RESPIRATOR OR RESPIRATORS OR VENTILATOR OR VENTILATORS OR -
S2
        12655
             CPAP OR CONTINUOUS () POSITIVE () AIRWAY () PRESSURE
s3
      766320
              FIT OR FITS OR FITTED OR FITTING
S4
      2155585
               TEST OR TESTS OR TESTED OR TESTING
      755343
              PRESSURE
S5
s6
      117136
              LEAK????
s7
         122 S1(S)S3(S)S4
        9151 S5(S)S6
S8
           2 S7(S)S8 [not relevant]
S9
S10
            5
              S7 AND S8
S11
            3
               S10 NOT S9
 11/3,AB,K/3
               (Item 1 from file: 16)
DIALOG(R) File 16: Gale Group PROMT(R)
(c) 2003 The Gale Group. All rts. reserv.
08453356
            Supplier Number: 72116203
Keys to effective noninvasive ventilation, Part 1: Initial steps.
MOORE, MICHAEL J.; SCHMIDT, GREGORY A.
The Journal of Critical Illness, v16, n2, p64
Feb, 2001
                     Record Type: Fulltext
Language: English
Document Type: Magazine/Journal; Refereed; Professional
              3830
Word Count:
     ABSTRACT: Noninvasive positive pressure ventilation (NIPPV) is the
standard of care for many patients with acute respiratory failure...
...a variety of masks available when fitting the patient; achieving
effective patient-ventilator interface, avoiding leaks, and maximizing
```

comfort are the most important initial considerations.

For patients in acute respiratory failure...improve the chances of success in achieving effective gas exchange.

Mask fit

The challenge of **fitting** the **mask** correctly is a common deterrent to NIPPV. Meduri and colleagues (21) **tested** a tight- **fitting** oronasal **mask** that had an inflatable cuff. Of 10 patients, 2 could not be **fitted**, I stopped using the **mask** because of discomfort, and 2 had problems with nasal bridge abrasions. In a subsequent study, 2 of 18 patients refused a **mask**, and 1 suffered mild facial pressure necrosis. (18)

In a large trial of 158 patients...

...mask in which added foam rubber reduced dead space and permitted a tight fit, preventing **leakage**; airflow and **pressure**-support levels were carefully adjusted to maximize ventilation and minimize **leaks**, and all patients tolerated the mask.

* Nasal versus oronasal masks: Both nasal (2,4,5... ...adequacy of the patient-ventilator interface.

It is very important to check closely for mask leaks and to adjust airflow and pressure -support levels. Inflatable cuffs, nasal bridge protection with a wound care dressing, and the availability...of the mask to minimize carbon dioxide rebreathing. It is important to check carefully

ASRC Searcher: Jeanne Horrigan Serial 10/035199 September 3, 2003

for leaks and to adjust airflow and pressure -support levels...

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September 3, 2003

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File 149:TGG Health&Wellness DB(SM) 1976-2003/Aug W3
File 636: Gale Group Newsletter DB(TM) 1987-2003/Sep 02
File 441:ESPICOM Pharm&Med DEVICE NEWS 2003/Aug W5
File 20:Dialog Global Reporter 1997-2003/Sep 03
       Items
               Description
Set
S1
       74599
               MASK? ?
S2
       16376
               RESPIRATOR OR RESPIRATORS OR VENTILATOR OR VENTILATORS OR -
            CPAP OR CONTINUOUS() POSITIVE() AIRWAY() PRESSURE
      667476 FIT OR FITS OR FITTED OR FITTING
s3
S4
     1802001
              TEST OR TESTS OR TESTED OR TESTING
S5
     1085942 PRESSURE
      159579 LEAK????
S6
         142
               S1(S)S3(S)S4
s7
        5169
               S5(S)S6
S8
S9
           9
               S7(S)S8
           5
               S2 AND S9
S10
           4
               RD (unique items)
S11
           4
               S9 NOT S10
S12
S13
           4 RD (unique items) [not relevant]
```

11/3,AB,K/1 (Item 1 from file: 149)

DIALOG(R) File 149:TGG Health&Wellness DB(SM)

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01820496 SUPPLIER NUMBER: 53979316 (USE FORMAT 7 OR 9 FOR FULL TEXT) Esophageal-Directed Pressure Support Ventilation in Normal Volunteers(*).

Barnard, Mathew; Shukla, Avinash; Lovell, Tim; Goldstone, John Chest, 115, 2, 482(1)

Feb, 1999

PUBLICATION FORMAT: Magazine/Journal; Refereed ISSN: 0012-3692 LANGUAGE: English RECORD TYPE: Fulltext TARGET AUDIENCE: Professional WORD COUNT: 4069 LINE COUNT: 00374

- ... increasingly sophisticated methods have been devised to make the interaction between the patient and the **ventilator** as sensitive as possible. To reduce the work performed during the initial phase of inspiration...
- ...The provision of ventilatory support for the patient is dependent on the ability of the **ventilator** to sense inspiration. Furthermore, airway pressure must be transmitted to the chest effectively such that alveolar pressure is positive during inspiration. Under ideal circumstances, the **ventilator** senses inspiration immediately and little pressure difference occurs across the lungs. This is usually achieved...
- ... When lung mechanics are abnormal, many factors prevent rapid detection of inspiration by the **ventilator**, the essential element being that transmission of the inspiratory signal to the **ventilator** is delayed. In addition, the preset pressure may be dissipated across the lungs and without...
- ...patient is often not recognized and described at the bedside as the patient "fighting the **ventilator**."(2) In this circumstance, there is a substantial amount of energy wasted resulting in patient discomfort.

It would be preferable to trigger the **ventilator** from a more direct indicator of inspiratory muscle contraction. The effect of the site of the inspiratory trigger on the patient- **ventilator** interface was investigated in a mechanical lung model by Takahashi and coworkers. (3) They found... ...baseline.

We aimed to investigate whether this was a potential strategy in humans. Supplying the **ventilator** with pressure signals from the esophagus

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implies that supported breaths are both triggered from and...

...ought to be minimized owing to early transmission of the pressure change signal to the **ventilator**, and the target pressure ought to be directly related to the ventilatory workload. A discrepancy...

...used could decrease the response time to initiation of gas flow, and potentially enhance patient- ventilator interaction and patient comfort. We have termed this mode esophageal directed pressure support (EDPS). We... ... of EDPS in human volunteers and measure the work of breathing and degree of patient ventilator desynchrony when compared with conventional IPS.

MATERIALS AND METHODS

Five normal human volunteers were studied25, who had no intercurrent disease.

Subjects breathed through a **ventilator** (Servo 900C; Siemens; Berkshire, UK) in pressure support mode. Flow and airway pressure were measured at the circuit-Y. Inspiratory and expiratory pressure-sensing transducers inside the **ventilator** were connected together with plastic tubing and joined by a three-way tap to the...

...connection allowed the Pes signal to be simultaneously monitored on the recording instruments.

Measurements

Airway **pressure** , Pes, and inspiratory flow rate were measured for each subject. Airflow was measured with a...

...Rudolph; Kansas City, MO) and volume was obtained from the integrated flow signal. A tight- fitting sealed face mask was strapped to each subject and tested to be leak free at 35 cm (H.sub.2)O. The pneumotachograph and airway pressure transducer were placed between the face mask and "Y" of the ventilator tubing. Pes was measured using a 10-cm latex balloon catheter filled with 0.5...

...placement of the balloon was according to the method described by Baydur et al.(4) **Pressure** and flow were calibrated with a water manometer and an air flowmeter (Platon; London, UK...

...breathing was achieved with linear 5-mm and 3-mm diameter resistors added to the $\mathbf{ventilator}$ circuit.

The **ventilator** controls were adjusted to enable sensing from Pes. In some subjects, resting Pes at the end of expiration was above zero. This was misinterpreted by the **ventilator** as a positive airway pressure when configured in EDPS mode. To avoid an increased load, whereby the negative deflection in Pes to successfully trigger the **ventilator** would have to equal the resting end expiratory Pes plus the triggering pressure, PEEP was applied. Since the **ventilator** is designed to trigger when airway pressure falls to a set level below PEEP, triggering...

...equal to resting Pes) minus the triggering pressure.

Protocol

Subjects breathed at rest without the **ventilator** for baseline measurements. The subjects then breathed through the **ventilator** in pressure support mode. The pressure support level was adjusted to produce a tidal volume...

...target Pes level of 0 cm (H.sub.2)O. The working pressure of the **ventilator** was adjusted until a target tidal volume of 10 mL/kg was achieved. Measurements were...

...time between the first negative Pes deflection and the initiation of inspiratory flow from the **ventilator**. Inspiratory response delays were measured for unloaded and 3-mm resistive breathing during IPS and...
...Pes was measured from the pressure tracings.

The mean of five representative breaths from each ventilator setting was used for analysis. Differences between IPS and EDPS were

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evaluated during each breathing...
...of ventilation.

Table 1--Inspiratory Time Delay Recorded in Five Normal Subjects
Breathing Through the **Ventilator** With Conventional IPS or From EDPS
Loaded

Unloaded (3 mm)

Mean inspiratory time delay (ms... ... 0.001, Table 2).

Table 2--PTP Recorded in Five Normal Subjects Breathing Through the **Ventilator** With IPS or From EDPS

Unloaded 5 mm 3 mm

Mean PTP during spontaneous 7...machine according to individual patient considerations. However, early efforts at allowing patients to breathe through **ventilator** circuitry were hampered by apparatus-imposed additional work loads due to unsophisticated valve technology. Advances in **ventilator** design have greatly reduced their resistance to spontaneous breathing and once again assisted or supported...

...ventilation to spontaneous breathing, (6,7) However, there remains a requirement for improving the patient **ventilator** interaction, particularly in patients with increased airway resistance.

EDPS involves triggering the **ventilator** from an earlier signal of inspiratory effort than the conventionally used airway pressure. This carries...

- ...might decrease that part of the work of breathing which is associated with triggering the **ventilator**. This is not only of theoretical concern. The endotracheal tube and apparatus can increase the...
- ...an earlier signal of inspiratory effort is a potential reduction in failing to trigger the **ventilator**. Dysynchrony describes a discrepancy between the frequency of inspiratory efforts and the frequency of supported...
- ...be greater than the sum of intrinsic PEEP plus trigger pressure to successfully trigger the **ventilator**. In the setting of significant intrinsic PEEP, the magnitude of pressure developed by the respiratory... ... as above, but implies that contractions smaller than this amount will fail to trigger the **ventilator**. These ineffective efforts may be uncomfortable, and also carry a metabolic cost. EDPS takes Pes...resistance and imposed work of the endotracheal tube and airways. Previous improvements to the patient **ventilator** interaction, such as flow triggering, have concentrated on measurements taken from and interventions directed at...
- ...standard esophageal balloon catheter by simply connecting it to the inspiratory pressure transducer of the **ventilator**. The inspiratory pressure transducer is readily accessible in the **ventilator** (Servo 900C) and inspiratory flow is switched on when inspiratory pressure is below the trigger...
- ...156:369-373
- (2) Rossi A, Appendini L. Wasted efforts and dysynchrony: is the patient- ventilator battle back? Intensive Care Med 1995; 21:867-870
- (3) Takahashi T, Takezawa J, Kimura...
 ...L, Rauss A, Benito S, et al. Comparison of three methods of gradual withdrawal from ventilator / support during weaning from mechanical ventilation. Am J Respir Crit Care Med 1994; 150:896 879
- (9) Jubran A, Van de Graaff WB, Tobin MJ. Variability of patientventilator interaction with pressure support ventilation in patients with chronic obstructive pulmonary disease. Am J Respir...
- ...11) Banner MJ, Kirby RR, Blanch PB. Site of pressure measurement during

ASRC Searcher: Jeanne Horrigan Serial 10/035199 September 3, 2003

spontaneous breathing with continuous positive airway pressure: effect on calculating imposed work of breathing. Crit Care Med 1992; 20:528-533

(12...

...et al. Additional work of breathing imposed by endotracheal tubes, breathing circuits, and intensive care **ventilators**. Crit Care Med 1989; 17:671-677

(14) Kimura T, Takezawa J, Nishiwaki K, et...

...Blanch PB, Kirby RR. Imposed work of breathing and methods of triggering a demand-flow, continuous positive airway pressure system. Crit Care Med 1993; 21:183-190

(17) Sassoon CSH, Gruer SE. Characteristics of the **ventilator** pressure and flow-trigger variables. Intensive Care Med 1995; 21:159-168

11/3,AB,K/2 (Item 2 from file: 149)

DIALOG(R) File 149:TGG Health & Wellness DB (SM)

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01609223 SUPPLIER NUMBER: 17928824 (USE FORMAT 7 OR 9 FOR FULL TEXT)

Institutional control measures for tuberculosis in the era of multiple drug resistance: ACCP/ATS Consensus Conference. (American College of Chest Physicians/American Thoracic Society)

Bates, Joseph H.; Nardell, Edward

Chest, v108, n6, p1690(21)

Dec, 1995

PUBLICATION FORMAT: Magazine/Journal ISSN: 0012-3692 LANGUAGE: English RECORD TYPE: Fulltext TARGET AUDIENCE: Professional

WORD COUNT: 18908 LINE COUNT: 01567

... for Occupational Health and Safety; OSHA=Occupational Safety and Health Administration; PAPR=powered air-purifying respirator; TB=tuberculosis; UV=ultraviolet; UVGI=ultraviolet germicidal irradiation

Key words: drug-resistant tuberculosis; nosocomial tubercolosis...not only an institution's need for special isolation rooms, but also its utilization of **respirators** for staff who care for patients in isolation. To our knowledge, there are no published...have been used as criteria in the absence of field trial data.

The ability of **respirators** to protect workers from certain airborne hazards has been well established. To the extent that **respirators** reduce the risk of inhaling droplet nuclei, they will reduce the chance of TB infection. **Respirators** require worker cooperation, but they cannot be worn continuously, and they will not be worn...

- ...be considered independently, since their effects are often complementary or additive in reducing risk. A **respirator** that is only 80% efficient in excluding droplet nuclei provides protection approximately equivalent to increasing...
- ...each doubling of effective ventilation reduces by half the risk of infection. If such a **respirator** was properly worn at the time the hazard was present, its protection would be equivalent...
- ...about two or three.[10] This change in ventilation, together with the use of a **respirator** that was only 80% efficient, would have been nearly fully protective against one of the...
- ...numbers of infectious particles in the air are few, further increments in filtration efficiency of **respirators** would be predicted to contribute minimal added protection. It is important to recognize that as part of a comprehensive infection control program, **respirators** need not be 100% efficient to be useful. In the two retrospective reviews of precautions implemented in hospitals in New York and Miami, previously cited, use of

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respirators less efficient than HEPA appear to have been effective when used together with administrative and environmental controls.[25,26] SELECTION OF RESPIRATORS

The reduction of transmission of infectious particles through the filtration material of face masks and respirators is accomplished by the impaction of particles on the filter or by electrostatic attraction. Five... ... the filtration material is face-seal leakage, the ability of unfiltered air to penetrate a respirator between the respirator 's edge and the wearer's face. [21,124-128] Both filtration efficiency and face-seal leakage determine the effective protection of personal respirators. In general, the more efficient the filtration material, the greater the airflow resistance, the greater...

...tendency for face-seal leakage, and the better the face-seal required. For example, two **respirators**, one with 99.97% filter efficiency (HEPA) and another with 95% filter efficiency, may provide similar protection if the face-seal leakage of both **respirators** averages 10 to 20%, as is often the case.[23]

The filtration characteristics of a variety of single-use masks and respirators have been assessed using mycobacterial aerosols of a particle size distribution believed to be representative...

...nuclei (1 to 5 [micro]m respirable particles).[129] In this investigation, face masks and **respirators** were sealed to the test apparatus to prevent leakage around the filtration material. As expected, HEPA **respirators** excluded a mean of more than 99.99% of the aerosolized mycobacteria. However, the filtration materials of most other masks and **respirators** tested were also highly efficient, trapping a mean of 96.9% or more of airborne mycobacterial aerosol. When masks and **respirators** are worn by people rather than sealed to a test apparatus, particles that reach the...

...likely to be due to leakage around the face seal. As of this writing, no respirator class other than HEPA is certified by the National Institute for Occupational Health and Safety...

...this document was approved for publication, NIOSH has finalized a new certification standard for particulate **respirators** and has certified a broad range of **respirator** models for TB protection. Additional information may be obtained by calling the NIOSH toll-free...

...testing procedures and standards have been proposed by NIOSH, which should result in certification of **respirators** of lower efficiency than HEPA for use in TB control.[130] CDC has proposed 95...

...10% face-seal leakage, as satisfactory protection for most TB control applications.[21] Positive-pressure **respirators** designed to minimize face-seal leakage (powered air-purifying **respirators** [PAPRs] and air-line **respirators**) are still recommended for the most hazardous applications, such as autopsies of patients with MDR TB.[21]

Face-seal leakage is affected by the match between size and shape of the face piece and facial features, facial hair, faulty respirator positioning, incorrect placement of head straps, facial oils, perspiration that leads to slippage, and damage to the respirator. Face-seal leakage is minimized by training regarding respirator usage and by fit testing. Only qualitative fit testing is possible for disposable respirators and should be done prior to respirator selection. In addition, workers should perform fit checks on themselves every time they put on a respirator, given the potential for damage as disposable respirators are reused. Disposable respirators can be reused by workers as long as the mask remains clean and structurally intact. [21] Given the limited availability of respirator sizes, their reuse, and the inability to

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quantitatively fit test disposable respirators, the potential for significant (10 to 20%) face-seal leakage remains. In contrast, PAPRs and line respirators can be quantitatively fit tested and have an estimated face leakage of only 2%.[21] About 15 to 20% of workers are unable to obtain a tight fit with available negative-pressure respirators, and these persons should use a PAPR when a respirator is required. Workers with beards cannot be fitted with negative-pressure respirators due to excessive face-seal leakage, and may also require positive-pressure respirators in hazardous settings. It is anticipated that once the new certification procedures for respirators are finalized and implemented, a wider range of sizes and styles of disposable and reusable respirators will become available.

The new certification procedures for **respirators** should lead to a better adaptation of technology developed for industrial applications to the very...

...considerations.[22-24,131-133]

Two recent cost-effectiveness analyses based on the current HEPA respirator recommendations calculated the cost of preventing a single case of TB. Based on survey data...

...TB case ranged from \$1.3 million under optimal conditions, to \$18.5 million if **respirator** utilization was suboptimal and more workers were exposed than necessary.[135] This approach to the issue of **respirators** has sparked controversy, with some critics pointing out that **respirators** should not be considered apart from administrative and environmental precautions.[136-142] While some critics...

...be more unethical not to consider cost, since the large sums of money spent on respirators will be unavailable for other, potentially more cost-effective interventions.[143] Whereas the broad application... ...to result in expenditures well out of proportion to risk, selective use of less costly respirators of sufficient efficacy pushes the cost-efficacy analysis back toward an acceptable balance.[22-24... ... is necessary.[143]

In view of both the potential utility and the inherent limitations of respirators to prevent TB transmission, and the cost considerations just discussed, efforts must be undertaken to tailor the application of respirators of various efficiencies to specific TB risks. Effective respiratory protection is currently required for three...
...procedure rooms, and in the transport of potentially infectious patients.[21,29] The use of respirators in isolation rooms and the categories of patients who require care in isolation rooms should affect patient care directly, but also result in the misallocation of limited funds for respirator usage. It is also important to emphasize that the risk for any particular patient will...

...provides a practical system that protects patients and employees. HIGHEST-RISK PATIENTS

Isolation room and **respirator** are required. The **respirator** may be any type approved by NIOS H for TB use. Depending on the risk of TB and of MDR TB, HEPA and positive-pressure **respirators** may be considered. Patients in this group have newly diagnosed conditions that are untreated, having...

...having pulmonary TB, but sputum smear laboratory reports are pending. $\mbox{HIGH RISK} \label{eq:higher_pulmon}$

Isolation room and **respirator** are required. Patients in this group include those who are smear positive and receiving effective... ...patient is clinically improved and cough frequency is reduced) and the requirement to use a **respirator** in the isolation room should be reviewed,

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with the expectation that in most cases its...

...time. Such patients may remain in isolation rooms, depending on the level of suspicion, but **respirators** are not required. This situation is most applicable in geographic areas of low risk where drug resistance is uncommon. In geographic areas at high risk for TB and drug resistance, **respirator** use should be required longer, pending repeated or more aggressive diagnostic studies.

Low Risk These...

...possible, but unlikely. These patients may or may not be placed in isolation, but a **respirator** is not required. This is most applicable to those areas of low risk where drug...ultraviolet radiation. NIOSH: Cincinnati, 1972; 1-5 [124] Hinds WC, Kraske G. Performance of dust **respirators** with facial seal leaks: I. Experimental. Am Ind Hyg Assoc J 1987; 48:836-41...

...694-99 [126] Chen CC, Lehtimaki M, Willeke K. Aerosol penetration through filtering facepieces and **respirator** cartridges. Am Ind Hyg Assoc J 1992; 53:566-74 [127] Chen CC, Ruuskanen J...

...129] Chen SK, Vesley D, Brosseau LM, et al. Evaluation of single-use masks and respirators for protection of health care workers against mycobacterial aerosols. Am J Infect Cont 1994; 22...Intern Med 1994; 120:964-65 [133] Jarvis WR, Bolyard EA, Bozzi CJ, et al. Respirators, recommendations, and regulations: the controversy surrounding protection of health care workers from tuberculosis. Ann Intern...

...Nettleman MD, Fredrickson M, Good NL, et al. Tuberculosis control strategies: the cost of particulate respirators . Ann Intern Med 1994; 121:37-40 [135] Adal KA, Anglim AM, Palumbo CL, et al. The use of high-efficiency particulate air-filter respirators to protect hospital workers from tuberculosis: a cost-effectiveness analysis. N Engl J Med 1994; 331:169-73 [136] Barnhart S, Beaudet N. Respirators and tuberculosis [letter]. Ann Intern Med 1995; 122:70 [137] Becket WS. Respirators and tuberculosis [letter]. Ann Intern Med 1995; 122:70 [138] Nettleman MD. Respirators and tuberculosis [letter]. Ann Intern Med 1995; 122:70-1 [139] Sobel E. HEPA respirators and tuberculosis in hospital workers [letter]. N Engl J Med 1994; 331:1658-59 [140] Sherertz RJ, Streed SA. HEPA respirators and tuberculosis in hospital workers [letter]. N Engl J Med 1994; 331:1659 [141] Brown V, Bishop C, Rutala WA, et al. HEPA respirators and tuberculosis in hospital workers [letter]. N Engl J Med 1994; 331:1659 [142] Adal KA, Anglim AM, Farr BM. HEPA respirators and tuberculosis in hospital workers [letter]. N Engl J Med 1994; 331:1659-60 [143...

11/3,AB,K/3 (Item 1 from file: 636)

DIALOG(R)File 636:Gale Group Newsletter DB(TM)

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02834745 Supplier Number: 45747603

Determination of inspiratory pressures and flow rates for work rate-dependent quantitative respiratory fit testing

Canadian Occupational Health & Safety News, v18, n34, pN/A

August 28, 1995

Language: English Record Type: Fulltext

Document Type: Newsletter; Trade

Word Count: 285

Quantitative respirator fit testing is used to select respirators for individual workers and to gain insight into potential contaminant leakage. Current fit test exercises are designed to

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primarily challenge the **respirator** face-piece-to-face seal. Inspiratory **pressure** across any break in the seal is also an important determinant of the amount of **leakage** through the break. **Fit tests** conducted at resting respiratory patterns may not be representative of **leakage** that occurs at respiratory patterns employed in the workplace. By design, the controlled negative **pressure fit test** method can control the driving force for **leakage** into a **respirator** by selecting a challenge **pressure** that represents actual use inspiratory pressures. In this study, mean inspiratory pressures and flow rates...

...at external work rates of 0, 180, 360 and 540 kg.m/ min. Effects of mask type and breathing resistance were determined using both half-mask and full-face respirators equipped with cartridges of relative low, medium and high breathing resistance. Inspiratory pressure was found to be strongly dependent on work rate and cartridge resistance. Mask type and gender also had significant effects on mean inspiratory pressure. Inspiratory flow rate was significantly affected by work rate and mask type. Data from the study can be used to conduct work rate-dependent fit testing with the controlled negative pressure method...

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File 155:MEDLINE(R) 1966-2003/Aug W5 5:Biosis Previews (R) 1969-2003/Aug W4 File 6:NTIS 1964-2003/Aug W5 File 34:SciSearch(R) Cited Ref Sci 1990-2003/Aug W4 File 434:SciSearch(R) Cited Ref Sci 1974-1989/Dec File 73:EMBASE 1974-2003/Aug W4 File 144: Pascal 1973-2003/Aug W4 File 440: Current Contents Search(R) 1990-2003/Sep 03 Items Description S1 11 MASK() FIT (2W) PRESSURE S2 5 RD (unique items) s3 0 S2/2003

1 \$2/2002 [a duplicate]

5/6,K/1 (Item 1 from file: 155)

4 S2 NOT S4

DIALOG(R)File 155:(c) format only 2003 The Dialog Corp. All rts. reserv. 10039540 21976666 PMID: 11980286

Follow-up and outcomes of nasal CPAP therapy in patients with sleep apnea syndrome.

Dec 2001

S4

S5

... hypertension. Side effects and compliance with CPAP are also influenced greatly by the adequacy of **mask fit** and **pressure** selection, which underlines the great importance of adequate technical expertise and patient education at the...

5/9/2 (Item 2 from file: 155)

DIALOG(R)File 155:MEDLINE(R)

(c) format only 2003 The Dialog Corp. All rts. reserv.

09843869 21655222 PMID: 11797024

Mask mechanics and leak dynamics during noninvasive pressure support ventilation: a bench study.

Schettino G P; Tucci M R; Sousa R; Valente Barbas C S; Passos Amato M B; Carvalho C R

Experimental Laboratory of Mechanical Ventilation, Respiratory ICU, Pulmonary Division, Hospital das Clinicas and Heart Institute, University of Sao Paulo Medical School, Sao Paulo, Brazil.

Intensive care medicine (United States) Dec 2001, 27 (12) p1887-91, ISSN 0342-4642 Journal Code: 7704851

Document type: Journal Article

Languages: ENGLISH

Main Citation Owner: NLM Record type: Completed Subfile: INDEX MEDICUS

OBJECTIVE: To study the mask mechanics and air leak dynamics during noninvasive pressure support ventilation. SETTING: Laboratory of a university hospital. DESIGN: A facial mask was connected to a mannequin head that was part of a mechanical respiratory system model. The mask fit pressure (P(mask-fit)) measured inside the mask's pneumatic cushion was adjusted to 25 cmH(2)O using elastic straps. Pressure support (PS) was set to ensure a maximal tidal volume distal to the mask (VT(distal)) but avoiding failure to cycle to exhalation. MEASUREMENTS: Airway pressure - fit mask occlusion pressure P (mask), (P(mask-occl)=P(mask-fit)-P(aw)), VT proximal (VT(prox)), distal to the mask (VT(distal)), air leak volume (Leak=VT(prox)-VT(distal)), and inspiratory air leak flow rate (difference between inspiratory flow ASRC Searcher: Jeanne Horrigan Serial 10/035199

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proximal and distal to the mask) were recorded. RESULTS: PS 15 cmH(2)0 was the highest level that could be used without failure to cycle to exhalation (VT(distal) of 585+/-4 ml, leak of 32+/-1 ml or 5.2+/-0.2% of VT(prox), and a minimum P(mask-occl) of 1.7+/-0.1 cmH(2)0). During PS 16 cmH(2)0 the P(mask-occl) dropped to 1.1+/-0.1 cmH(2)0, and at this point all flow delivered by the ventilator leaked around the mask, preventing the inspiratory flow delivered by the ventilator from reaching the expiratory trigger threshold. CONCLUSION: P(mask-fit) and P(mask-occl) can be easily measured in pneumatic cushioned masks and the data obtained may be useful to guide mask fit and inspiratory pressure set during noninvasive positive pressure ventilation.

Tags: Human; Support, Non-U.S. Gov't

Descriptors: *Masks; *Positive-Pressure Respiration--instrumentation--IS

; Equipment Failure Analysis; Manikins; Respiratory Mechanics

Record Date Created: 20020117
Record Date Completed: 20020306

5/9/3 (Item 3 from file: 155)

DIALOG(R) File 155: MEDLINE(R)

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02715826 78144148 PMID: 637791 Record Identifier: 78144148

Effects of using long breathing hoses upon mask pressure.

Cooke J P; Olson R M; Maloney T M

Aviation, space, and environmental medicine (UNITED STATES) Feb 1978,

49 (2) p365-70, ISSN 0095-6562 Journal Code: 7501714

Document type: Journal Article

Languages: ENGLISH

Main Citation Owner: NLM Other Citation Owner: NASA Record type: Completed Subfile: INDEX MEDICUS

Effects of using oxygen breathing hoses from 0.9 to 8.2 m (3 to 27 ft) fit upon mask pressure during 0.75 to 12-s and mask decompressions from 2,438 m (8,000 ft) to either 6,096, 10,668, or 15,240 m (20,000, 35,000 or 50,000 ft) were determined. Peak mask pressures and duration of high mask pressure were related to mask fit, mask and hose stretch compliance, pressure differential, decompression rate, and other factors, with mask pressure increasing with hose length. Peak mask pressures frequently exceeded 80 mm Hg, a high pressure associated with increased incidence of pulmonary damage. Cargo-type aircraft, however, have sufficiently large volumes so that they will not decompress rapidly enough to have high mask pressure, even with an 8.2-m long hose. Long breathing hoses should not be used in smaller aircraft since small cabin volume will result in rapid decompression rates and high mask pressure. Above a flight altitude of 2,438 m, oxygen should always be breathed if hoses longer than 2.9 m (9 ft) are used. This would help prevent hypoxia, associated with the need to deplete air in the hose before oxygen is breathed, should cabin pressure be lost at a high altitude. The fastest decompression rates compatible with preventing mask pressures from exceding 80 mm Hg during decompressions to different altitudes with different length breathing hoses are given.

Tags: Human

Descriptors: *Aerospace Medicine; *Masks; Aircraft; Decompression; Pressure

Record Date Created: 19780517
Record Date Completed: 19780517

ASRC Searcher: Jeanne Horrigan Serial 10/035199 September 3, 2003 File 16:Gale Group PROMT(R) 1990-2003/Sep 02 File 88:Gale Group Business A.R.T.S. 1976-2003/Sep 02 File 149:TGG Health&Wellness DB(SM) 1976-2003/Aug W3 File 180: Federal Register 1985-2003/Sep 02 File 624:McGraw-Hill Publications 1985-2003/Sep 02 Items Description Set S1 7 MASK() FIT (2W) PRESSURE s2 5 RD (unique items) s3 0 S2/2003 S4 0 S2/2002 2/6,K/2 (Item 1 from file: 149) DIALOG(R) File 149:(c) 2003 The Gale Group. All rts. reserv. 01909938 SUPPLIER NUMBER: 62495033 (USE FORMAT 7 OR 9 FOR FULL TEXT) Effects of Augmented Continuous Positive Airway Pressure Education and Support on Compliance and Outcome in a Chinese Population(*). WORD COUNT: 5207 LINE COUNT: 00440 1 month and 3 months to deal with any problem with the CPAP device or mask fit , and CPAP pressure was adjusted if necessary. Augmented Support: In addition to the basic-support (BS) group, patients... 2/3,AB/3 (Item 1 from file: 180)

DIALOG(R) File 180: Federal Register

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DIALOG Accession Number: 02442355 Supplier Number: 980100514

Respiratory Protection

Volume: 63 Issue: 5 Page: 1152

CITATION NUMBER: 63 FR 1152
Date: THURSDAY, JANUARY 8, 1998

Serial 10/035199 September 3, 2003

```
File 350:Derwent WPIX 1963-2003/UD,UM &UP=200355
File 347: JAPIO Oct 1976-2003/Apr(Updated 030804)
File 371: French Patents 1961-2002/BOPI 200209
       Items
               Description
S1
      180496
               MASK? ?
S2
       17916
               RESPIRATOR OR RESPIRATORS OR VENTILATOR OR VENTILATORS OR -
            CPAP OR CONTINUOUS() POSITIVE() AIRWAY() PRESSURE
              FIT OR FITS OR FITTED OR FITTING
s3
     1003949
      631817 TEST OR TESTS OR TESTED OR TESTING
S4
S5
     1443335 PRESSURE
s6
      222985 LEAK????
s7
         645 IC=A61M-016/06
        3523
              IC=A62B-007
S8
S 9
        1695
               IC=A62B-009
S10
           6
               S1 AND S3 AND S4 AND S5 AND S6
S11
           2
               S10 AND S7:S9
               S10 NOT S11
S12
11/34/1
            (Item 1 from file: 350)
DIALOG(R) File 350: Derwent WPIX
(c) 2003 Thomson Derwent. All rts. reserv.
015420071
            **Image available**
WPI Acc No: 2003-482211/200345
 Nasal mask for delivering supply of gases to user, comprises engager
 including attachment portion able to be engaged with headgear strap, and
 slidingly engage headgear strap with patient interface
Patent Assignee: FISHER & PAYKEL HEALTHCARE LTD (FISH-N)
Inventor: GRADON L G; MCAULEY A E; MILIVOJEVIC I; NIGHTINGALE C E; SMITH N
Number of Countries: 101 Number of Patents: 001
Patent Family:
                    Date
                            Applicat No
                                           Kind
                                                  Date
                                                           Week
Patent No
            Kind
WO 200339637 A1 20030515 WO 2002NZ227
                                           A 20021025
                                                          200345 B
Priority Applications (No Type Date): NZ 515257 A 20011105
Patent Details:
Patent No Kind Lan Pg
                       Main IPC
                                    Filing Notes
WO 200339637 A1 E 28 A61M-016/06
   Designated States (National): AE AG AL AM AT AU AZ BA BB BG BR BY BZ CA
   CH CN CO CR CU CZ DE DK DM DZ EC EE ES FI GB GD GE GH GM HR HU ID IL IN
   IS JP KE KG KP KR KZ LC LK LR LS LT LU LV MA MD MG MK MN MW MX MZ NO NZ
   OM PH PL PT RO RU SD SE SG SI SK SL TJ TM TN TR TT TZ UA UG US UZ VC VN
   Designated States (Regional): AT BE BG CH CY CZ DE DK EA EE ES FI FR GB
   GH GM GR IE IT KE LS LU MC MW MZ NL OA PT SD SE SK SL SZ TR TZ UG ZM ZW
Abstract (Basic): WO 200339637 Al
       NOVELTY - A nasal mask for delivering a supply of gases to a user
    comprises an engager (606, 607) adapted to slidingly engage a headgear
    strap (604, 605, 609, 611) with a patient interface.
       The engager comprises an attachment portion (608, 610) able to be
    engaged with the headgear strap
```

DETAILED DESCRIPTION - A nasal mask comprises:

- (i) a patient interface in fluid communication with the supply of gases, when in use;
- (ii) headgear strap attached to or around the head of the user; and (iii) engager adapted to slidingly engage the headgear strap with the patient interface.

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The engager comprises an attachment portion able to be engaged with the headgear strap. The engagement between the headgear strap and the engager is caused by the releasable engagement of a protrusion (612, 613), located on one of the attachment portion and the headgear strap, into a complementary shaped aperture (614, 615) located on one of the engager and the headgear strap.

An INDEPENDENT CLAIM is also included for a continuous positive airways **pressure** system, comprising:

- (a) a pressurized source of gases;
- (b) a transport mechanism in fluid communication with the pressurized source adapted to convey the gases; and
- (c) a nasal **mask** in fluid communication with the transport mechanism.

USE - The nasal **mask** is used for delivering supply of gases to user, useful in continuous positive airways **pres**sure system (claimed), used as therapy from obstructive sleep apnea.

ADVANTAGE - The invention is more comfortable for the user to wear and reduces the side **leakage** as compared with **masks** of the prior art.

DESCRIPTION OF DRAWING(S) - The draw shows a front view of a sliding strap with clipping attachment mechanism for use with the inventive nasal $\max k$.

Slider (601)
First end (602)
Second end (603)
Headgear strap (604, 605, 609, 611)
Engager (606, 607)
Attachment portion (608, 610)
Protrusion (612, 613)
Complementary shaped aperture (614, 615)
pp; 28 DwqNo 6/9

Technology Focus:

TECHNOLOGY FOCUS - INSTRUMENTATION AND $\mbox{\bf TESTING}$ - Preferred Device: The patient interface is a nasal $\mbox{\bf mask}$.

The nasal **mask** comprises a body portion having an inlet receiving the supply of gases; and sealer attached to or integrated with the body portion.

The sealer is adapted to seal against the facial contours of the user.

The engager is a slider (601) adapted to allow the headgear strap movement with respect to the nasal <code>mask</code>, while still providing compressive force on the sealer to ensure the supply of gases is delivered to the user without <code>leakage</code>. It comprises a restrainer(s) on the body portion, where in use, the slider is restrained in dimension(s), which can slide easily within other dimension(s) by the restrainer and can be easily disengaged.

The headgear strap is a strap having two ends, each having the protrusion.

The slider has a first end (602) and a second end (603), where the aperture is located in each of the first and second ends; and a section along it's length that is narrower in diameter than the rest of the sliders length, where the narrower section is easily fittable into the restrainer(s), to allow for the ease of **fitting** or removal of the slider within the restrainer(s).

The restrainer is vertically adjustable upon the body portion in a freely moveable manner or lockable in vertical position(s Derwent Class: B07; P33

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International Patent Class (Main): A61M-016/06

12/26,TI/3 (Item 3 from file: 350)

DIALOG(R) File 350: Derwent WPIX

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004229262

WPI Acc No: 1985-056141/198509

In vivo dermal absorption testing of laboratory animal - uses head covering breathing mask supplied with air under pressure

12/7,K/1 (Item 1 from file: 350)

DIALOG(R) File 350: Derwent WPIX

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013881759 **Image available**
WPI Acc No: 2001-365971/200138

Strapless respiratory facial mask , has nose piece with central opening for gas supply adhered along cushioning layer of gasket

Patent Assignee: BELFER W A (BELF-I); PETILLO P (PETI-I)

Inventor: BELFER W A; PETILLO P

Number of Countries: 001 Number of Patents: 001

Patent Family:

Patent No Kind Date Applicat No Kind Date Week
US 6196223 B1 20010306 US 9858437 A 19980410 200138 B
US 99301876 A 19990429

Priority Applications (No Type Date): US 99301876 A 19990429; US 9858437 A 19980410

Patent Details:

Patent No Kind Lan Pg Main IPC Filing Notes
US 6196223 B1 25 A63B-018/08 CIP of application US 9858437
Abstract (Basic): US 6196223 B1

NOVELTY - A mask has a gasket (20) with a cushioning layer (22) and an adhesive layer (24). A triangular nose piece (60) whose central opening is connected to gas supply, is adhered along the edges of cushioning layer to form a peripheral seal. The central section of the nose piece includes an opening for connecting a tube (90) which supplies gas.

DETAILED DESCRIPTION - The central section of nose piece is shaped for receiving the wearer's nose. The tubular section includes an annular central opening for alignment with the opening (68) of the central section. The gas supply is connected to one end of the tubular section and check valves are mounted at the other end of the tubular section. The adhesive layer includes double-sided adhesive film, double-sided adhesive tape, pressure -sensitive adhesive, pressure -sensitive glue, pressure -sensitive gel or other adhering material. Peelable protective covering is provided for protecting skin attaching surface of adhesive layer. The peelable protective covering is made of paper, cellophane, polyvinyl chloride (PVC), aluminum foil, polyethylene (PE), teflon, silicone tapes, gels, plastic film or composites. The nose piece is made from thermoplastic material selected from the group consisting of ethylene vinyl acetate, methyl vinyl acetate, methyl acrylate, polypropylene, polyethylene, ELVAX, polytetrafluoroethylene resin, urethane, styrene, acrylic, Telfon, Sorbothane, carboxylate compound, or viscoelastic thermoset compound. The cushioning layer is selected from the group consisting of elastomeric compounds such as urethanes, polyvinylchloride foam, polytetrafluoroethylene foam, acrylic foam, polystyrene foam,

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polyethylene foam, urethane foam, ethylvinyl acetate, silicones, rubber and/or neoprene.

An INDEPENDENT CLAIM is also included for strapless assembling and applying method which involves molding nose piece to custom fit the facial contours and skin of the person's face in preparation for adhering the laminated gasket. One or more sealing sections are trimmed to match the person's facial contours. The peelable protective covering is removed from the peripheral sealing section. The sealing sections of peripheral sealing is adhered to the person's facial contours and skin to obtain an airtight seal between moldable laminated gasket of mask and person's face. The nose piece is heated using hair blower and soaked in boiling hot water for 15-30 sec until the thermoplastic material is pliable. The rotatable respiratory hose is connected to the central opening (74) for expelling of carbon dioxide (CO2) gas out of facial mask when in use. A sub-nasal respiratory hose is connected to central opening for connecting to pressurized or non-pressurized gas supply in order to provide respiratory therapy to the wearer.

USE - For customizing to the wearer's face used in respiratory therapy, sleep medicine, anesthesia delivery, diagnostic **testing**, high altitude breathing, military, mining, chemical, metal fabrication and other industrial applications, occupational safety and fire fighting, laboratory procedures, woodworking, metal working, paint spraying and in any environments where dust and other air borne contaminants are present.

ADVANTAGE - The respiratory facial mask has the capability of being sealed tightly to the wearer's facial contours and skin without any skin trauma, irritation or inflammatory reaction to the skin surface. The mask receives pressurized or non-pressurized gases such as air, pure oxygen, anesthesia, steam-vapors, atomized or nebulized medicines without leakage of substances through the seal to the surroundings atmosphere or causing any decreases in gaseous pressure within the mask. The mask is simple and cheap. The mask is comfortable to wearer and gives aesthetically pleasing appearance when worn. The mask can be worn for a long period of time for diagnostic testing or medical treatment in order to achieve higher success rate of treatment by the user. The mask kit is assembled easily and man produced in automated and economical manner.

DESCRIPTION OF DRAWING(S) - The figure shows the exploded front view of strapless respiratory facial $\max k$.

Moldably laminated gasket (20) Cushioning layer (22) Adhesive layer (34) Nose piece (60) Central section (62) Opening (68) Central opening (74) Tube (90) pp; 25 DwgNo 3A/16 Derwent Class: A96; P36 International Patent Class (Main): A63B-018/08 12/7,K/2 (Item 2 from file: 350) DIALOG(R) File 350: Derwent WPIX (c) 2003 Thomson Derwent. All rts. reserv. 012540322 **Image available** WPI Acc No: 1999-346428/199929

September 3, 2003

```
Sleep apnea positive airway pressure treatment system with different
 applied pressure during exhalation and inhalation
Patent Assignee: RESPIRONICS INC (RESP-N)
Inventor: CATTANO J M; ESTES M C
Number of Countries: 001 Number of Patents: 001
Patent Family:
Patent No Kind
                    Date
                            Applicat No
                                          Kind Date
            A 19990511 US 91786269
                                          A 19911101 199929 B
US 5901704
                                               19930823
                            US 93110372
                                           Α
                            US 96645110
                                          Α
                                              19960513
Priority Applications (No Type Date): US 93110372 A 19930823; US 91786269 A
 19911101; US 96645110 A 19960513
Patent Details:
Patent No Kind Lan Pg Main IPC
                                    Filing Notes
US 5901704 A
                      A61M-016/00
                                    CIP of application US 91786269
                                    Div ex application US 93110372
                                    CIP of patent US 5239995
                                    Div ex patent US 5551418
Abstract (Basic): US 5901704 A
       NOVELTY - A pressure transducer (138) provides a signal
   indicative of the instantaneous flow rate of air to the patient (12).
   This is compared with a time-averaged value of the airflow and,
   depending on whether it exceeds or is lower than the average value, a
   CPU (136) decides that inhalation or exhalation takes place and
   triggers the application of a high or low pressure accordingly (14, 26).
       DETAILED DESCRIPTION - Before initiation of treatment, the
   apparatus will output a leakage test pressure (166) to
   temporarily overpressurize the gas flow circuit for a preset period of
   time, using a timer (170), during which the patient can fit the mask
     (22) to his face and adjust it to ensure minimum leakage .
       The average pressure is slowly ramped up when therapy is initiated.
       USE - For treatment of sleep apnea.
       ADVANTAGE - By applying a lower pressure during exhalation (which
   requires less pressure that inhalation for preventing apnea),
   difficulties in exhaling caused by excessive pressure are reduced
   thereby increasing patient comfort. By minimizing unwanted system
   leaks prior to operation, the average system pressure can likewise
   be minimized, again increasing patient comfort. By ramping the
   pressure slowly when therapy is initiated, the patient's transition to
   sleep is eased.
       DESCRIPTION OF DRAWING(S) - The drawing shows a schematic diagram
   of the system.
       Patient (12)
       Flow generator (14)
        Pressure controller (26)
        Mask (22)
       CPU (136)
        Pressure transducer (138)
        Leakage test pressure controller (166)
       Timer (170
Derwent Class: P34; S05; T01; T06
International Patent Class (Main): A61M-016/00
12/7,K/4
             (Item 4 from file: 350)
DIALOG(R) File 350: Derwent WPIX
```

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ASRC Searcher: Jeanne Horrigan

Serial 10/035199 September 3, 2003

001706365

WPI Acc No: 1977-E2852Y/197721

Apparatus for testing gas mask for leaks - contains reversible

pump, pressure gauge with stopcock and balloon

Patent Assignee: AUERGESELLSCHAFT GMBH (AUER) Number of Countries: 001 Number of Patents: 002

Patent Family:

 Patent No
 Kind
 Date
 Applicat No
 Kind
 Date
 Week

 DE 2550594
 A 19770518
 197721 B
 B
 19790613
 197925

Priority Applications (No Type Date): DE 2550594 A 19751107 Abstract (Basic): DE 2550594 A

The apparatus consists of a **pressure** gauge, to which two flexible hoses are **fitted**. One leads to a connector that **fits** the inlet valve of the gas **mask** to be **tested**, and the other leads to a reversible (**pressure** and suction) pump, preferably a rubber bulb.

The **pressure** gauge is **fitted** with a stopcock on the side nearer the pump.

The whole apparatus is mounted on a board which drops loosely into a box; the box has compartmented trays for tools and spares. The **tests** are made with the **mask fitted** over an inflated balloon; the hand pump **fits** the balloon and can be used to inflate it.

Derwent Class: P35; S02

International Patent Class (Additional): A62B-027/00; G01M-003/02

ASRC Searcher: Jeanne Horrigan Serial 10/035199 September 3, 2003 File 348: EUROPEAN PATENTS 1978-2003/Aug W04 File 349:PCT FULLTEXT 1979-2002/UB=20030828,UT=20030821 Items Description S1 68219 MASK? ? RESPIRATOR OR RESPIRATORS OR VENTILATOR OR VENTILATORS OR -S2 8916 CPAP OR CONTINUOUS() POSITIVE() AIRWAY() PRESSURE s3 328693 FIT OR FITS OR FITTED OR FITTING TEST OR TESTS OR TESTED OR TESTING S4 431474 526604 PRESSURE **S**5 S6 107812 LEAK???? s7 207 IC=A61M-016/06 S8 438 IC=A62B-007 377 IC=A62B-009 S9 153 S10 S1(S)S3(S)S4 S11 26812 S5(S)S6 8 S12 S10(S)S11 1 S12 AND S7:S9 [a duplicate] S13 7 S12 NOT S13 S14 (Item 1 from file: 349) 14/3,AB/1 DIALOG(R) File 349: PCT FULLTEXT (c) 2003 WIPO/Univentio. All rts. reserv. 00919450 **Image available** CHARACTERISATION OF MASK SYSTEMS CARACTERISATION DE SYSTEMES DE MASQUES RESPIRATOIRES Patent Applicant/Assignee: RESMED LTD, 97 Waterloo Road, North Ryde, New South Wales 2113, AU, AU (Residence), AU (Nationality), (For all designated states except: US) WICKHAM Nicola Frances (executrix for the deceased inventor), 20 Hampden Road, Five Dock, New South Wales 2046, AU, AU (Residence), AU (Nationality), (Designated only for: US) Inventor(s): WICKHAM Peter John (deceased), Legal Representative: DAVIDSON Geoffrey Robert (et al) (agent), Halford & Co., Level 7, 1 Market Street, Sydney, New South Wales 2000, AU, Patent and Priority Information (Country, Number, Date): WO 200253217 A1 20020711 (WO 0253217) Patent: WO 2001AU1673 20011224 (PCT/WO AU0101673) Application: Priority Application: US 2000258606 20001229 Designated States: AU JP US (EP) AT BE CH CY DE DK ES FI FR GB GR IE IT LU MC NL PT SE TR Main International Patent Class: A61M-016/00 Publication Language: English Filing Language: English Fulltext Word Count: 10801 English Abstract A method and a CPAP apparatus (10) for characterizing a plurality of different mask systems (14), e.g., masks and hoses, are provided. The CPAP apparatus (10) can be calibrated for different mask systems (14) and hoses (16) by including sensors (13,15) configured to measure flow and

A method and a CPAP apparatus (10) for characterizing a plurality of different mask systems (14), e.g., masks and hoses, are provided. The CPAP apparatus (10) can be calibrated for different mask systems (14) and hoses (16) by including sensors (13,15) configured to measure flow and pressure at a flow generator (12) of the CPAP apparatus (10). When the flow generator (12) is fitted to a new mask system (14), or any changes are made to an existing mask system (14), mask or patient interface (34) and/or hose (16), a method of calibrating the flow generator (12) for the new mask system (14), mask (34) and/or hose (16) is provided. The method

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includes determining air flow characteristics of the hose (16) using flow measurements made during a first test period when the flow through the mask system (14) is open, measuring or estimating pressure in the mask system (14) during a second test period when the flow through the mask system (14) is blocked and determining air flow characteristics of the diffuser (36) of the mask system (14) using the air flow characteristics of the air delivery hose (16) determined during the first test period and the pressure measurements made during the second test period.

Legal Status (Type, Date, Text)

Publication 20020711 A1 With international search report.

Examination 20020808 Request for preliminary examination prior to end of 19th month from priority date

14/7/2 (Item 2 from file: 349)

DIALOG(R) File 349: PCT FULLTEXT

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00892561 **Image available**

BI-LEVEL FLOW GENERATOR

GENERATEUR DE DEBIT A DEUX NIVEAUX AVEC REGLAGE MANUEL DE DEPERDITION STANDARD

Patent Applicant/Assignee:

MALLINCKRODT INC, 675 McDonnell Boulevard, P.O. Box 5840, St. Louis, MO 63134, US, US (Residence), US (Nationality)

Inventor(s):

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HANSEN Gary L, 19085 Pheasant Circle, Eden Prairie, MN 55346, US, Legal Representative:

REPPER George R (et al) (agent), Rothwell, Figg, Ernst & Manbeck, P.C., 1425 K Street, N.W., Suite 800, Washington, DC 20004, US,

Patent and Priority Information (Country, Number, Date):

Patent: WO 200226304 A2-A3 20020404 (WO 0226304)
Application: WO 2001US30456 20010928 (PCT/WO US0130456)

Priority Application: US 2000672955 20000929

Designated States: CA JP

(EP) AT BE CH CY DE DK ES FI FR GB GR IE IT LU MC NL PT SE TR

Main International Patent Class: A61M-016/00

Publication Language: English

Filing Language: English Fulltext Word Count: 4388

English Abstract

An apparatus for delivering a breathing gas to a patient includes a display, a storage device programmed to hold different purge hole leak profiles for a variety of mask types, and a selection mechanism for selecting one of the profiles so that accurate values of tidal volume, excess leak and peak flow may be calculated and shown on the display. The displayed excess leak value can be used to correct the fit of the mask.

Legal Status (Type, Date, Text)

Publication 20020404 A2 Without international search report and to be republished upon receipt of that report.

Examination 20020620 Request for preliminary examination prior to end of 19th month from priority date

Search Rpt 20020808 Late publication of international search report Republication 20020808 A3 With international search report.

Search Rpt 20020808 Late publication of international search report

September 3, 2003

Correction 20030220 Corrected version of Pamphlet: pages 1/5-5/5, drawings, replaced by new pages 1/5-5/5; due to late transmittal by the receiving Office

Republication 20030220 A3 With international search report. Claim

- 1 An apparatus for delivering a breathing gas to a
- 2 patient comprising
- a blower that generates a flow of a breathing gas;
- a gas flow rate sensor positioned to sense the flow of
- 5 breathing gas generated by said blower;
- a memory device containing a plurality of purge hole leak
- 7 profiles corresponding to specific types of breathing
- 8 appliances;

means for selecting one of said plurality of purge hole

leak profiles from said memory device; and

- a microprocessor programmed to calculate at least one of excess leak, tidal volume, and peak flow using a flow rate measured by said gas flow rate sensor and the selected purge hole leak profile.
- 2 The apparatus of claim 1, further comprising a
- 2 display device in communication with said microprocessor, said
- 3 display device displaying at least one of the calculated
- 4 excess leak, tidal volume, and peak flow in response to a
- 5 signal generated by said microprocessor.
- 3 The apparatus of claim 2, further comprising an external communication port in communication with said microprocessor. 17
- 4 The apparatus of claim 3, wherein said blower, said gas flow rate sensor, said memory device, said microprocessor, said display device, and said external communication port are part of a gas flow generating unit.
- 5 The apparatus of claim 4, further comprising a
- 2 computer, wherein said gas flow generating unit is connected to said computer via said external communication port.
- 6 The apparatus of claim 5, wherein said computer is programmed to display at least one of the calculated excess leak, tidal volume, and peak flow in response to a signal
- generated by said microprocessor.

 7 The apparatus of claim 5, wherein said computer is programmed to permit selection of one of a plurality of purge
- hole leak profiles from said memory device. 8 The apparatus of claim 4, wherein said gas flow generating unit includes a console and wherein said selecting means includes at least one control on said console.
- 9 The apparatus of claim 1, wherein each purge hole
- leak profile is a mathematical function describing purge hole
 18
- leak over a range of gas pressures for a specific type of mask.
- 10 The apparatus of claim 1, wherein each purge hole leak profile is a set of purge hole leak values corresponding to aset of gas pressure values for a specific type of mask.
- I 11. A method for delivering a breathing gas to a user comprising the steps of $% \left\{ 1,2,\ldots ,n\right\}$
- generating a flow of a breathing gas using a gas flow generator;

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measuring the flow rate of the breathing gas; selecting one of a plurality of purge hole leak profiles from a memory device; and calculating at least one of excess leak, tidal volume, and peak flow using the measured flow rate and the selected 10 purge hole leak profile. 12 The method of claim 11, wherein said calculating step is performed by a microprocessor disposed within the gas flow generator. 13 The method of claim 11, wherein said calculating step is performed by a computer communicating with the gas flow generator via an external connection. 19 14 The method of claim 11, and further comprising, 2 after said calculating step, the step of displaying at least one of the calculated excess leak, tidal volume, and peak flow on a visual display device. 15 The method of claim 14, wherein said displaying step includes displaying at least one of the calculated excess leak, tidal volume, and peak flow on a display panel of the gas flow generator. 16 The method of claim 14, wherein said displaying step 2 includes displaying at least one of the calculated excess leak, tidal volume, and peak flow on a computer communicating with the gas flow generator via an external connection. 17 The method of claim 11, and further comprising the 2 steps of measuring gas pressure and determining a purge hole leak flow rate using the measured gas pressure. 18 The method of claim 11, and further comprising the step of retrieving the selected purge hole leak profile from a computer communicating with the gas flow generator via an external connection. - 20 . The method of claim 11, wherein each purge hole leak profile is a mathematical function describing purge hole leak over a range of gas pressures for a specific type of breathing appliance. 20 The method of claim 11, wherein each purge hole leak profile is a set of purge hole leak values corresponding to a set of gas pressure values for a specific type of breathing appliance... (Item 3 from file: 349) 14/3,AB/3 DIALOG(R) File 349: PCT FULLTEXT (c) 2003 WIPO/Univentio. All rts. reserv. 00753138 **Image available** STACKABLE FILTER DEVICE DISPOSITIF DE FILTRE EMPILABLE Patent Applicant/Assignee: VASE TECHNOLOGY, 250 Canal Street, Lawrence, MA 01840, US, US (Residence) , US (Nationality) Inventor(s): ESWARAPPA Muniyapla T, 2 McKenney Circle, Andover, MA 01810, US Legal Representative: RAGUSA Joseph W, Fitzpatrick, Cella, Harper & Scinto, 30 Rockefeller Plaza, New York, NY 10112-3801, US

Patent and Priority Information (Country, Number, Date):

WO 200066248 A1 20001109 (WO 0066248)

ASRC Searcher: Jeanne Horrigan

Serial 10/035199 September 3, 2003

WO 2000US11363 20000428 (PCT/WO US0011363) Application: Priority Application: US 99131834 19990429; US 99447131 19991122 Designated States: AE AG AL AM AT AU AZ BA BB BG BR BY CA CH CN CR CU CZ DE DK DM DZ EE ES FI GB GD GE GH GM HR HU ID IL IN IS JP KE KG KP KR KZ LC LK LR LS LT LU LV MA MD MG MK MN MW MX NO NZ PL PT RO RU SD SE SG SI SK SL TJ TM TR TT TZ UA UG UZ VN YU ZA ZW (EP) AT BE CH CY DE DK ES FI FR GB GR IE IT LU MC NL PT SE (OA) BF BJ CF CG CI CM GA GN GW ML MR NE SN TD TG (AP) GH GM KE LS MW SD SL SZ TZ UG ZW (EA) AM AZ BY KG KZ MD RU TJ TM Main International Patent Class: B01D-046/24 International Patent Class: A62B-023/02; B01D-029/54 Publication Language: English Filing Language: English Fulltext Word Count: 8800 English Abstract

A stackable filter device for filtering an input to a source of suction comprises: a substantially hollow filter pad having first and second filter walls constructed of a filter material, the periphery of the first filter wall being sealingly engaged to the periphery of the second filter wall to form the filter pad, each of the filter walls having an aperture. The first and second filter walls each have an annular member fixedly contacted to the circumferential edge of the aperture. The annular members support the aperture, and are structured so as to integrally form connectors operable to removably connect the filter device to the source of suction or to an additional filter device on a first side of the filter device and to a sealing end cap or an additional filter device on a second side of the filter device. The filter device preferably includes a tubular stiffening member passing through the filter device. The stiffening member is rigidly attached at each end thereof to one of the annular members. The stiffening member comprises a perforated tubular shaft forming an air passage through the filter device.

Legal Status (Type, Date, Text)

Publication 20001109 A1 With international search report.

Publication 20001109 A1 Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.

Examination 20010201 Request for preliminary examination prior to end of 19th month from priority date

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14/3,AB/4 (Item 4 from file: 349)
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DIALOG(R) File 349: PCT FULLTEXT

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00464526 **Image available**

APPARATUS AND METHOD FOR ENHANCING COMFORT AND FOR FIT TESTING OF DISPOSABLE FACE MASKS

APPAREIL ET PROCEDE SERVANT A AMELIORER LE CONFORT ET A VERIFIER L'ETANCHEITE DE L'ADHERENCE DE MASQUES JETABLES

Patent Applicant/Assignee:

TECNOL MEDICAL PRODUCTS INC,

Inventor(s):

RUMMLER Joseph A, BOWEN Michael L, BRUNSON Kevin K,

Patent and Priority Information (Country, Number, Date):

Patent: WO 9854991 A1 19981210

ASRC Searcher: Jeanne Horrigan

Serial 10/035199 September 3, 2003

Application: WO 98US11418 19980603 (PCT/WO US9811418)

Priority Application: US 97869564 19970604

Designated States: AL AM AT AU AZ BA BB BG BR BY CA CH CN CU CZ DE DK EE ES FI GB GE GH GM GW HU ID IL IS JP KE KG KP KR KZ LC LK LR LS LT LU LV MD MG MK MN MW MX NO NZ PL PT RO RU SD SE SG SI SK SL TJ TM TR TT UA UG UZ VN YU ZW GH GM KE LS MW SD SZ UG ZW AM AZ BY KG KZ MD RU TJ TM AT BE CH CY DE DK ES FI FR GB GR IE IT LU MC NL PT SE BF BJ CF CG CI CM GA GN ML MR NE SN TD TG

Main International Patent Class: A41D-013/00

Fulltext Word Count: 11337

English Abstract

A disposable face mask or disposable respirator including a filter body capable of filtering hazardous materials and/or dangerous airborne pathogens and forming a substantially fluid tight seal between the periphery of the respective face mask or respirator and adjacent portions of a wearer's face. Each disposable face mask or respirator having a filter body with a connector attached thereto and extending therefrom for use in coupling one end of a flexible hose with the respective face mask or respirator. The other end of the flexible hose may be attached to a source of vacuum or a source of low pressure air. For some applications, a single portable source may be used to apply either vacuum or positive low pressure air to the other end of the flexible hose. The connector, flexible hose and source of either vacuum or positive low pressure air improves the apparent breathability and comfort during extended periods of wearing the respective face mask or respirator.

14/3,AB/5 (Item 5 from file: 349)

DIALOG(R) File 349: PCT FULLTEXT

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00369699 **Image available**

RESPIRATOR HAVING THERMOCHROMIC FIT-INDICATING SEAL RESPIRATEUR A JOINT INDICATEUR D'AJUSTAGE THERMOCHROMIQUE

Patent Applicant/Assignee:

MINNESOTA MINING AND MANUFACTURING COMPANY,

Inventor(s):

SPRINGETT James E,

BARRETT Leonard W,

Patent and Priority Information (Country, Number, Date):

Patent: WO 9710027 A1 19970320

Application: WO 96US12711 19960805 (PCT/WO US9612711)

Priority Application: US 95526909 19950912

Designated States: AL AM AT AU AZ BB BG BR BY CA CH CN CU CZ DE DK EE ES FI GB GE HU IL IS JP KE KG KP KR KZ LK LR LS LT LU LV MD MG MK MN MW MX NO NZ PL PT RO RU SD SE SG SI SK TJ TM TR TT UA UG UZ VN KE LS MW SD SZ UG

AM AZ BY KG KZ MD RU TJ TM AT BE CH DE DK ES FI FR GB GR IE IT LU MC NL

PT SE BF BJ CF CG CI CM GA GN ML MR NE SN TD TG

Main International Patent Class: A62B-027/00

International Patent Class: G01M-03:04

Publication Language: English

Fulltext Word Count: 3823

English Abstract

Respirator (10) has a respirator body (11) that is configured to fit over the nose and mouth of a wearer. A thermochromic material (18) is positioned on the respirator body (11) such that the thermochromic material (18) makes thermal contact with the wearer's face when the respirator (10) is worn. The contact causes the thermochromic material

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(18) to change color to allow the wearer to determine if a proper fit has been established.

14/7/7 (Item 7 from file: 349)

DIALOG(R) File 349: PCT FULLTEXT

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00138038

A NON-INVASIVE, QUANTITATIVE METHOD FOR FIT TESTING RESPIRATORS AND CORRESPONDING RESPIRATOR APPARATUS

METHODE QUANTITATIVE NON INVASIVE DE TEST ADAPTATIF DE MASQUES RESPIRATOIRES ET APPAREIL RESPIRATOIRE CORRESPONDANT

Patent Applicant/Assignee:

UNIVERSITY OF CINCINNATI,

Inventor(s):

WILLEKE Klaus,

Patent and Priority Information (Country, Number, Date):

Patent: WO 8702898 A1 19870521

Application: WO 86US2438 19861111 (PCT/WO US8602438)

Priority Application: US 85207 19851112

Designated States: AT AU BE CH DE FR GB IT JP LU NL SE

Main International Patent Class: A62B-027/00

Publication Language: English Fulltext Word Count: 15218

English Abstract

A method and apparatus for conducting the method for non-invasive, quantitative respirator fit testing. The method includes the steps of having the wearer properly position the respirator over his nose and mouth, inhale to create a negative pressure inside the respirator cavity volume, hold his breath and record the pressure differential versus time decay rate between the <code>pressure</code> inside the respirator cavity volume and that of the surrounding environment. The method may also include establishing a leakhole of known dimension, repeating the above steps and determining the volume of the respirator cavity based upon the results of the recorded differential pressure versus time by comparing the result to calibration curves. The apparatus of the present invention includes modifying a conventional face mask respirator by providing the respirator with a pressure sensor and a leakhole of known dimension. Preferably, the apparatus can also include a calculator to continuously calculate a quantitative factor to indicate the degree of protection, which is based upon the volume of the respirator cavity divided by the volumetric flow rate through the leakhole or holds of unknown dimension and location for a standard unit of time, given an initial negative pressure in the respirator cavity. Claim

- 1 In a face mask respirator for use in a hazardous air environment, said respirator having an air inlet and an air outlet and forming a respirator cavity volume when. In the face mask respirator of claim 1, wherein said aperture comprises a tube of known dimensions, said tube being molded into said face mask respirator...
- 3 In the face mask respirator of claim 1, wherein said means to open and close said aperture is a flow control valve.
- 4 In the face mask respirator of claim 1, wherein said means for sensing comprises a tube molded into the said face mask respirator, and a pressure sensor coupled to said tube.
- 5 In the face mask respirator of claim 1, wherein said means for sensing comprises a pressure sensor securely mounted on said face mask respirator, an

ASRC Searcher: Jeanne Horrigan Serial 10/035199 September 3, 2003

opening being fluidly coupled to said pressure sensor, said @opening terminating within said respirator cavity volume.

- 6 In the face mask respirator of claim 1, further .comprising a canister having an internal volume, said canister being secured to said face mask respirator over I and about said air inlet whereby said internal volume of said canister is in communication with said respirator cavity volume.
- 7 In the face mask respirator of claim 6, wherein said aperture comprises a tube molded into said canister, said tube having known internal dimensions.
- 8 In the face mask respirator of claim 7, wherein said means for sensing comprises a hole molded into said canister, and a pressure sensor coupled with said hole whereby said pressure sensor can measure the pressure in the respirator cavity volume by measuring the pressure in said canister.
- 9 In the face mask respirator of claim 1, further comprising means to record the pressure within said respirator cavity volume with time, said means to record being coupled with means for sensing.
- 10 In the face mask respirator of claim 9, said means to record being mounted on said face mask respirator.
- 11 In the face mask respirator of claim 9, wherein said means to record comprises a strip chart.
- 12* In the face mask respirator of claim 117 wherein said strip chart is mounted on said face mask respirator and is alogarithmic strip chart.
- 13 In the face mask respirator of claim 1, said means to sense includes a signal means to inform the wearer when the fit of said face mask respirator is insufficient.
- 14a In the f ace mask res pi ra to r of claim 13, wherein said signal is an audible signal.
- 15a A canister for testing the degree of fit between a conventional face mask respirator and the face of a wearer, said canister comprising a hollow member, a first portion of said hollow member having an opening therein, said opening designed to be in communication with an air inlet opening of a conventional face mask respirator, and a second portion of said hollow member, said second portion having an aperture of known dimensions, and a means for sensing the pressure within said hollow member.
- 16 The canister of claim 15, wherein said second portion further includes a second aperture having dimensions sufficient to permit normal breathing when said canister is attached to said face mask respirator.
- 17 The canister of claim 16, wherein each of said aperture of known dimensions and said second aperture include means to open and close said apertures,
- 18 The canister of claim 17, wherein said means to. open and close comprises flow control valves.
- 19 The canister of claim 15, wherein said means to sense the pressure comprises a third aperture and a remote pressure sensor fluidly coupled to said aperture,
- 20 The canister of claim 15, wherein said means to sense the pressure comprises a third aperture and a pressure sensor fluidly coupled to said third aperture, said pressure sensor securely fastened to said canister.
- 2 1 The canister of claim 15, wherein said means to sense the pressure includes means to record the pressure with time.
- 22 The canister of claim 21, wherein said means to sense also includes a pressure sensor indicating the pressure within said hollow member, said pressure sensor being molded on said canister so as to be readable by the wearer.
- 23 A face mask respirator for use in a hazardous air environment, said respirator comprising a cup-like member having resilient edges and adapted to fit over the face of a wearer forming a respirator cavity volume between the

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face of a wearer and the cup-like member, said cup-like member including an exhalation valve, an inhalation valve, an air purifying canister designed to be in communication with said inhalation valve, said air purifying canister having means to secure or remove it from said cup-like member, and a test canister, said test canister having means to secure or remove it from said cup-like member, the test canister having means to sense the pressure in said respirator cavity volume, and a leakhole of known dimensions, whereby when it is desired to test said face mask respirator, said air purifying canister is removed from said cup@like member and replaced with said canister.

- 24 A non-invasive, quantitative method for fit testing a face mask respirator based upon the pressure and volume in the respirator cavity volume, comprising:
 - 1) donning a respirator;
 - 2) sealing all known inlets into the respirator cavity volume of said face mask respirator;
 - 3) creating a negative pressure within the respirator cavity volume;
 - 4) recording the pressure within the respirator cavity volume with time;
 - 5) determining a quantitative factor based upon the press-ure and volume within said respirator cavity volume for a specific period o time to in'dicatge the degree of protection the face mask respirator provides the wearer.
- 25 The method of claim 24, wherein the step of To sealing comprises covering all known inlets with the palms of the wearer's hands.
- 26 The method of claim 24, wherein the step of sealing comprises replacing at least one of the air is purifying canister with a test canister.
- 27 The method of claim 26, wherein the step of sealing further comprises replacing the cemaining air purifying canisters with sealed canisters whereby the interior of said sealed canister is exclusive of the respirator cavity volume.
- 28 The method of claim 24, wherein the step of creating a negative pressure within the respirator cavity 2.5 volume includes inhaling by the wearer to obtain the negative pressure.
- 29 The method of claim 24, wherein the step of recording the pressure within the respirator cavity volume with time includes recording the pressure and time on a strip-chart.
- 30 The method of claim 24, wherein the step of determining the fit factor includes determining the volume of the respirator cavity by leaking air into the respirator cavity through a leakhole of known dimensions.
- L. 31* The method of claim 30, wherein the step of determining the volume of the respirator cavity includes comparing the slope of the graph of the pressure versus time of the leakhole of known dimensions with a series of slopes of known volume s on a calibration graph to determine the volume of said respirator cavity.
- 32. The method of claim 24, wherein said respirator is an air supplied respirator. LO $\,$
- 33 The method of claim 24, wherein said respirator is selected from the class comprising a half-mask respirator, a quarter-mask respirator, a full respirator and a helmet-hood respirators is
- 34 The method of claim 24, wherein the step of determining a quantitative factor includes an alarm means whereby when said quantitative factor is below a predetermined quantity, said alarm means is activated.

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Stradling, J., The Lancet, Jan 1997

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Neuromuscular Disorders, May 1998

...retarded. In Italy and the UK, the orthopedic intervention to fit the orthoses is kept at a minimum and is mainly done by...free from secretions such as continuous positive airway pressure (CPAP). She also should teach the parents assisted coughing...

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■ 6. Pulmonary dysfunction and its management in post-polio patients

Bach, J.R. / Tilton, M., Neurorehabilitation, Mar 1997

hard...least 3 or 4 commercially available CPAP masks as interfaces for IPPV to determine ..oxygen and continuous positive airway pressure (CPAP) approaches are taken. It is the ones which best optimize fit, seal, and comfort. If none are adequate...

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Highlights from the 1996 American Society of Anesthesiologists' Annual Meeting Panel on: Admission and Discharge... 7.

Twersky, R.S., Ambulatory Surgery, May 1997

..tests, as the specificity and sensitiv- ity of the laboratory test varies. resulting in false posi- tives and negatives. In the...More pa- tients within the abnormal preoperatis-e coagulation test groups had more operations postponed and more additional tests...

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1. Determination of mask fitting pressure and correct mask fit Brewer, Gregory Newton / Colla, Gregory Alan / Farrugia, Steven Paul / Somaiya, Chinmayee, Jul 2002 the functional mode is a manual mode, then the mask-fit test pressure is the current set bressure. If the functional mode is the automatic titration mode, the mask-fit test pressure is the 95.sup.th percentile pressure of the previous	Or refine using: All of the words

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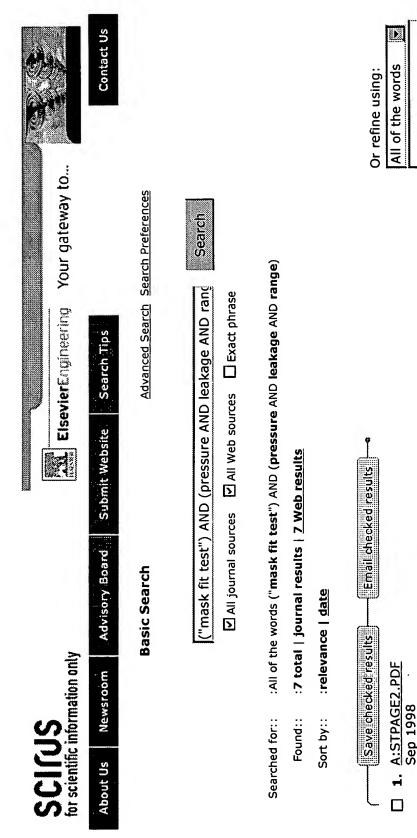
...a controller having a control of said flow generator and programmed to cause a mask-fit test pressure to be applied at the mask, said test pressure being determined as a

percentile...

[http://www.uspto.gov/web/patents/patog/week31/OG/html/...]

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peripheral...perform a Valsalva maneuver to equalize pressure in their ears). A joint and...mask (the joint service general purpose mask [JSGPM]) will allow for better ...barriers. Currently, PPE consists of a mask, special over-garments, and gloves more hits from [http://chppm-www.apgea.army.mil/desp/info_papers/Force...] service lightweight... similar results Oct 2000 067-107 7

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...projects, which can aid in attaining better and, from a long-range viewpoint, more

economical paint jobs. 2. Applicablity. This...Maintenance Painting Approaches .

http://www.usace.army.mil/inet/information/usace-docs/...]

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6-3 Application of **Test** Patches of Coating Materials

..or the M-41 Protection Assessment **Test** System (PATS) is required to determine proper Sep 1998

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fit. Proper mask size will be determined upon issueand the outsert removed) you can	as follows: AFH 32-4014, Volume
fit. Proper mask size will be	fit the mask as follows: AF

[http://www.afrc.af.mil/AFEPLTEMP/STDPUBS2/pubs/af/32/a...] similar results

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Jul 2001

pressure coolant injection (HPCI) system...radiographic examination and test results of surveillance test results: 2 + 2.2.28 Dry Chemical...ultrasonic tests performed on high ...core isolation cooling, high pressure coolant injection, control rod...procedures and butt welds 10R2...

[http://www.nrc.gov/NRR/OVERSIGHT/ASSESS/REPORTS/pilg_2...]

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☐ 6. Level-A-Rpt-0.PDF

Feb 2002

... simulant is conducted to measure any aerosol leakage into the suit. During the test, the people in the suits are moving in ways...simulant) vapor, is used to measure any vapor **leakage** into the suit. This **test** was conducted on six suits one from each... [http://www.chem-bio.com/resource/dp_levela_executive_r...]

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7. 001-15

Oct 2000

Recommendation. Additional...research is needed on **mask** seals and **mask fit.**..should deploy the M41 Mask Fit Test kit more widely. Finding. Leakage around closures in ..critical problem. The leakage can be attributed to...face, and (2) improper fit. personal...

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